Ebola Virus
Preparedness and Response Plan

Version History			
Version	Date	Description	Principal Author
1.0	18 August 2014	Initial version	D. Charles Hunt
1.1	02 October 2014	Minor edits with updated guidance and references	D. Charles Hunt
2.0	21 October 2014	Updated Background and Situation Update Updated exposure category criteria Updated monitoring and health care / public health actions to be taken for persons exposed to Ebola virus Added more detailed information regarding infection prevention, environmental infection control, laboratory testing, and public health management of suspected EVD cases and contacts Added detailed packaging and shipping guidance for laboratory testing Added animal management section Formatting and structural changes	D. Charles Hunt
2.1	27 October 2014	Updated PPE guidance and simplified format Added waste management flowchart	D. Charles Hunt
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4.0	12 November 2014	Updated Appendix 4 to include guidance on PPE trained observers/ assistants Included flexibility for direct active monitoring in Management of Person Potentially Exposed to Ebola Virus Added Biohazardous Waste Storage guidance to Appendix 7 Revised Appendix 1 - Risk Assessment	D. Charles Hunt
5.0	04 December 2014	Added Mali to list of countries affected and updated status of the Democratic Republic of Congo Other minor and technical revisions incorporated for clarification	D. Charles Hunt
6.0	19 December 2014	Added information regarding additional preparedness and response planning activities Updated guidelines regarding risk assessment and categories, direct active monitoring, and active monitoring	D. Charles Hunt
7.0	27 February 2015	Updated information on Mali to reflect the World Health Organization declaration that it was Ebola-free as of 18 January 2015 Updated monitoring and movement guidelines to remove prohibition on commercial travel for persons in the “Low (but not zero” risk category	D. Charles Hunt
8.0	25 September 2015	Updated information on Liberia Added information on exposure risk assessment for health care workers caring for patients with EVD in Kansas to include that patient symptoms of vomiting, diarrhea, or obvious bleeding shall be considered Updated guidelines regarding exposure risk categories for determination of health care and public health actions to be taken Updated information on management of persons under public health monitoring who develop symptoms compatible with EVD Added information regarding framework for tiered approach to hospital preparedness Updated personal protective equipment guidance to adopt Centers for Disease Control and Prevention (CDC) recommendations Updated laboratory guidance to adopt CDC recommendations	D. Charles Hunt

Principal author
D. Charles Hunt, MPH
State Epidemiologist and Director
Bureau of Epidemiology and Public Health Informatics

Contributors
Robert Moser, MD, Secretary and State Health Officer (former)
William Bider, Director, Bureau of Waste Management
N. Myron Gunsalus, Director, Kansas Health and Environmental Laboratories
Sheri Tubach, MPH, MS, Director of Infectious Disease Epidemiology and Response

Background and Situation Update

The ongoing epidemic of Ebola virus disease (EVD) in West Africa is the largest in history. It was first reported in March, 2014 in the West African nations of Guinea, Liberia, and Sierra Leone. Travel-associated cases have subsequently appeared in Nigeria, Senegal, Spain, the United States, Mali, the United Kingdom, and Italy. Limited local secondary transmission was reported in some of these countries. As of 13 September 2015, more than 28,000 total cases and 12,000 deaths had been reported in the three primary countries of Guinea, Liberia, and Sierra Leone. Updated case counts from the epidemic are available from the U.S. Centers for Disease Control and Prevention (CDC) website at http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/index.html. Counts are frequently updated.

Although the incidence of EVD in the most affected countries has decreased substantially since peaking in late 2014 and early 2015, the epidemic continues in Guinea and Sierra Leone. On 09 May 2015, the World Health Organization (WHO) had declared the end of the epidemic in Liberia, and the U.S. CDC classified Liberia as a country "with former widespread transmission and current, established control measures". However, on 29 June 2015, a new confirmed case was reported – the first since 20 March 2015. Five additional cases were subsequently reported. The last two reported cases tested negative for a second time on 23 July, and all contacts have completed their 21-day follow-up period.

A map of Africa is provided in Figure 1. The CDC has maintained Level 3 Travel Advisories (Avoid Nonessential Travel) for Guinea and Sierra Leone. Effective 03 September 2015 the CDC Travel Advisory for Liberia was downgraded to Level 1 (Practice Usual Precautions). Additional details can be found at http://wwwnc.cdc.gov/travel/diseases/ebola. Humanitarian assistance is considered ***essential*** travel.

Figure 1: Map of Africa (Courtesy Nations Online Project)

On 30 September 2014, the CDC confirmed the first imported case of EVD in the United States in a person in Dallas, Texas who had traveled from Liberia. This patient was hospitalized at Texas Presbyterian Hospital, and died on Wednesday, 08 October 2014. On 12 October 2014, a health care worker at Texas Presbyterian Hospital who provided care for the index patient tested positive for Ebola virus infection. On 15 October 2014, a second health care provider who had provided care for the index patient tested positive for Ebola virus infection.

Although Ebola virus transmission from an infected patient to two health care providers has now been documented in the Texas case, sustained transmission of EVD in Kansas or the United States is highly unlikely. However, so long as the outbreak in West Africa continues, additional cases among persons with recent travel to EVD-affected countries could be anticipated.

Health care workers are advised when evaluating any patients with signs and symptoms compatible with EVD to collect a thorough travel and exposure history, and ensure that such history is communicated to the entire care team to assist with clinical decision-making. If a patient meets the case definition, has signs and symptoms compatible with EVD, and traveled within one of the affected countries in the preceding 21 days, they should be immediately isolated with appropriate protections put in place to protect public and personal health.

Kansas Preparedness and Response Planning Activities

Preparedness and Response Plan Development

In response to the outbreaks in Africa and the potential for travel-associated cases occurring in Kansas, the Kansas Department of Health and Environment (KDHE) has developed this preparedness and response plan. The first version was published 18 August 2014. The document has been periodically updated as needed.

The KDHE Ebola Virus Preparedness and Response Plan is an adjunct planning document to the Kansas Response Plan (state all hazards preparedness plan) and its companion Biological Incident Annex. In addition, the KDHE Bureau of Epidemiology and Public Health Informatics has updated its Viral Hemorrhagic Fever Disease Investigation Guideline.

Stakeholder Engagement

On 10 October 2014 KDHE held its first update meeting for stakeholders. The purpose of the meeting was to present the KDHE Ebola Preparedness and Response Plan. The meeting was well attended, with participants joining in person and via telephone / webinar.

Beginning 16 October 2014 KDHE initiated weekly teleconferences with population health partners (including local health departments, hospitals, and others) focusing exclusively on Ebola virus. During these teleconferences, KDHE provided situational updates, revisions to the KDHE Ebola Virus Preparedness and Response Plan, documents and other resources, and responded to participant questions. These teleconferences continued through 20 November 2014. Participation in these teleconferences ranged from 140 lines on 20 November to 750 lines on 16 October. Beginning November 25, 2014, KDHE resumed its regular schedule for population health teleconferences, with an update on Ebola virus being included as part of the agenda.

Also on 16 October 2014, KDHE established a dedicated email address (Response2014@kdheks.gov) for interested parties to utilize to submit questions, comments, or concerns.

Senior KDHE staff involved in developing and managing the Ebola Preparedness and Response Plan and attended the first in a series of meetings with each of the seven Regional Health Care Coalitions throughout the state on 17 November 2014. These meetings have been well attended, ranging from 74 participants to 118 participants to date.

Planning Seminar and Tabletop Exercises

On 28 October 2014, KDHE, in conjunction with the Kansas Division of Emergency Management (KDEM), conducted an executive state-level Ebola virus disease planning seminar. This seminar included senior staff representatives from 20 state agencies and focused primarily on state response activities.

A state-level tabletop exercise, planned by KDHE and KDEM staff, was conducted on 20 November 2014. This exercise also focused on state-level response activities should a case of Ebola virus disease be reported in Kansas. On 16 December 2014, all state agency public information officers that would likely be involved the Kansas Joint Information Center participated in a tabletop exercise. Finally, a second state-level tabletop exercise was held on 09 January 2015, which focused on additional preparedness and response capabilities.

Regional Medical Bio-Response Teams and KDHE Bio- Strike Team

KDHE has utilized the Kansas System for the Early Registration of Volunteers (K-SERV) to recruit health care workers and other staff who would be willing to volunteer their services to respond in the event a case of Ebola virus disease occurs in Kansas. Teams would deploy to assist local facilities that receive a patient with Ebola when requested by those facilities and their duties would depend on their skills, credentials and training. KDHE additionally has identified a Bio-Strike Team comprised of KDHE staff that would be able to provide technical assistance to and help identify resources for a facility with an Ebola patient.

Federal Cooperative Agreement Funding

KDHE has been awarded a total of $3,546,642 in federal cooperative agreements to enhance preparedness and capacity for response to EVD and other high-consequence infectious pathogens throughout the public health and healthcare systems. A brief summary of each of these programs is provided here.

Epidemiology and Laboratory Capacity for Infectious Diseases (ELC): $788,118 (supplement)

The Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) cooperative agreement is an ongoing program in the Bureau of Epidemiology and Public Health Informatics. It provides funding to support crosscutting infectious disease epidemiology, laboratory, and health information systems as well as specific funding for foodborne illness, healthcare-associated infections, West Nile virus and other arboviral diseases, influenza surveillance, vaccine-preventable diseases, rabies, and others.

The Ebola virus supplemental funding will be utilized to enhance infection prevention capacity in hospitals and biosafety and biosecurity in clinical laboratories. Specific components include working with hospitals to conduct comprehensive assessments of infectious disease preparedness and infection prevention capabilities, improving outbreak detection and reporting, developing and implementing a validation plan for healthcare-associated infections, and conducting risk

assessments at the Kansas Health and Environmental Laboratories and sentinel laboratories throughout the state and developing action plans to mitigate identified gaps.

Public Health Emergency Preparedness (PHEP): $1,678,016 (supplements)

Two supplemental cooperative agreement awards were provided by the PHEP program. Funding from these awards provided additional support for further development and implementation of Ebola virus and other infectious disease preparedness and planning activities, as well as support for public health monitoring of travelers from Ebola virus-affected countries and other preventive measures, purchase of personal protective equipment, laboratory equipment and supplies, securing a safe transport mechanism for suspected or confirmed patients with EVD, provision of technical assistance and training, and enhancing community-level preparedness. Local health departments received a total of $1,099,914 in contractual awards.

Hospital Preparedness Program: $1,080,508 (stand-alone award)

The primary objectives of the Hospital Preparedness Program Ebola virus cooperative agreement include: 1) Expansion of the current Ebola Preparedness and Response Plan to include the tiered approach for response, Just in Time training, transport of patients, and Ebola virus disease patient care; 2) Development of MOU(s) with the regions' Ebola Treatment Center(s) to be shared with assessment hospitals and healthcare coalitions; 3) Further development of Ebola/highly infectious disease exercise materials to include a secret shopper scenario and patient care simulation; 4) PPE purchase and sustainment PPE trainings; 5) Purchase a cache of corrugated drums to have on hand for hospitals when needed; and 5) Development of a Standard Operating Procedure template to assist EMS providers and local hospitals to develop an Ebola waste disposal plan.

About Ebola Virus

Most notably, Ebola virus causes Ebola hemorrhagic fever (Ebola HF), which is one of numerous viral hemorrhagic fevers. It is a severe, often fatal disease in humans and nonhuman primates (such as monkeys, gorillas, and chimpanzees).

Ebola HF is caused by infection with a virus of the family *Filoviridae*, genus *Ebolavirus*. When infection occurs, symptoms typically begin within eight to 10 days. The first *Ebolavirus* species was discovered in 1976 in what is now the Democratic Republic of the Congo near the Ebola River. Since then, outbreaks have appeared sporadically.

There are five identified subspecies of *Ebolavirus*. Four of the five have caused disease in humans: Ebola virus (*Zaire ebolavirus*); Sudan virus (*Sudan ebolavirus*); Taï Forest virus (*Taï Forest ebolavirus*, formerly *Côte d'Ivoire ebolavirus*); and Bundibugyo virus (*Bundibugyo ebolavirus*). The fifth, Reston virus (*Reston ebolavirus*), has caused disease in nonhuman primates, but not in humans.

The natural reservoir host of Ebola virus remains unknown. However, on the basis of available evidence and the nature of similar viruses, researchers believe that the virus is zoonotic (animal-borne) with bats being the most likely reservoir. Four of the five subtypes occur in an animal host native to Africa.

A host of similar species is probably associated with Reston virus, which was isolated from infected cynomolgous monkeys imported to the United States and Italy from the Philippines. Several workers in the Philippines and in U.S. holding facility outbreaks became infected with the virus, but did not become ill.

Since first being discovered in 1976, there have been more than 30 events of cases and outbreaks of Ebola virus disease (range: 1 human case to 425 human cases prior to the current outbreaks).

Signs and Symptoms

Symptoms of Ebola HF typically include fever, headache, joint and muscle aches, weakness, diarrhea, vomiting, stomach pain, and loss of appetite. Some patients may also experience a rash, red eyes, hiccups, cough, sore throat, chest pain, difficulty breathing, difficulty swallowing, and bleeding inside and outside of the body.

The typical incubation period (time between exposure and onset of symptoms) is eight to 10 days, though the range is two days to 21 days.

Transmission of Ebola Virus

The natural reservoir (i.e., host species) of Ebola virus and the manner by which the first human infection(s) occur at the beginning of an outbreak have not been definitively determined. The prevailing hypothesis is that human infections first occur through contact with an infected animal.

Ebola virus can be transmitted from person to person by:

- Direct contact with the blood or secretions of an infected person
- Exposure to objects (such as needles) that have been contaminated with infected secretions

Ebola virus is not transmitted from person to person through the air, water, or food.

Diagnosis

Diagnosis of EVD during the early course of illness may be difficult because the symptoms are not specific to EVD. If EVD is suspected, several laboratory tests are available to confirm the diagnosis. Additional details regarding laboratory testing are presented in the "Evaluation and Management of Suspected EVD Cases: Information for Health Care Providers, Emergency Medical Services Personnel, and Public Health Officials" section below.

Treatment

Standard treatment for EVD is still limited to supportive therapy. This consists of:

- Balancing the patient's fluids and electrolytes
- Maintaining their oxygen status and blood pressure
- Treating them for any complicating infections

Management of Persons Potentially Exposed to Ebola Virus and Suspected EVD Cases

The Guinean Ministry of Health, the Ministry of Health and Sanitation of Sierra Leone, and the Ministry of Health and Social Welfare of Liberia are working with national and international partners to investigate and respond to the outbreak. The CDC is assisting with active screening and education efforts on the ground in the affected countries to prevent sick travelers from getting on planes. In addition, airports in the affected countries are screening all outbound passengers for Ebola symptoms, including fever, and passengers are required to respond to a health care questionnaire.

In October, 2014 the CDC and U.S. Customs and Border Protection implemented entry screening of passengers arriving from the Ebola-affected countries of Guinea, Liberia, and Sierra Leone at five U.S. airports – New York's JFK International Airport, Washington-Dulles, Newark, Chicago-O'Hare, and Atlanta. Together, more than 94 percent of all travelers to the Ebola-affected countries had been arriving through these five airports; on 21 October 2014, the U.S. Department of Homeland Security announced that all travelers from these three countries in West Africa would arrive in the U.S. at one of the five designated airports. The screening consists of observing entering travelers for general overt signs of illness, asking a series of health and exposure questions, providing information about Ebola virus disease and self-monitoring for symptoms, and temperature measurement by trained medical staff.

Nonetheless, there is the potential for additional persons to have been exposed to Ebola virus in the affected countries to arrive in the United States, including Kansas.

The Kansas Department of Health and Environment's Bureau of Epidemiology and Public Health Informatics (KDHE-BEPHI) has developed a Disease Investigation Guideline for viral hemorrhagic fever (www.kdheks.gov/epi/Investigation_Guidelines/VHF_Disease_Investigation_Guideline.pdf), which has been updated. This Ebola Virus Preparedness and Response Plan is not intended to replace the KDHE Disease Investigation Guideline, but rather provides specific information relevant to the current epidemic in West Africa.

Risk Assessment

As noted above, the CDC and Customs and Border Protection (CBP) are conducting entry screening of travelers who have traveled from or through Guinea or Sierra Leone. The CDC will distribute contact information for screened passengers to the state health department based on the passenger's designation.

Effective 17 June 2015, CDC discontinued routine notification to state health departments of persons arriving in the U.S. from Liberia (as long as persons had no travel to Guinea or Sierra Leone in the previous 21 days) unless that the state specifically requested to receive such notifications. Kansas requested to continue receiving notifications for these travelers and has relayed this information to the appropriate local health department.

Effective 21 September 2015, following a CDC determination that the risk of Ebola importation into the United States by travelers from Liberia is low and that Liberia has implemented effective control measures, CDC has announced several changes regarding travelers from Liberia:

- Travelers from Liberia will no longer be funneled through the five selected U.S. airports.
- CDC will no longer send Epi-X notices to state, local, and territorial health departments regarding travelers from Liberia.
- In accordance with other changes implemented in June 2015, travelers from Liberia will no longer undergo active monitoring, maintain daily contact with state health departments, or do "self-observation" for 21 days after departure from Liberia to check for symptoms consistent with Ebola.

For persons arriving in Kansas with known travel to or residence in one of the currently affected countries (Guinea or Sierra Leone) within the previous 21 days, KDHE or the local health department will conduct a risk assessment (Appendix 1). This risk assessment is based on exposure guidelines recommended by the CDC. The health care facility and public health actions to be taken are based on three defined levels of exposure risk and whether or not persons are experiencing any potential signs or symptoms of EVD. There are special considerations for health care and laboratory workers.

The risk assessment will focus on contact with persons known or suspected to have EVD, including visiting or working in health care facilities, household contact with or providing in-home care to persons with potential EVD, or other activities that could pose a risk of transmission.

As in most previous outbreaks, those at highest risk of EVD are health care workers and family and other close contacts of patients with EVD. The risk assessment includes details for health care workers regarding contact with patients known or suspected to have EVD and infection prevention practices, including use of personal protective equipment and potential breaches in infection prevention practices.

Persons undergoing a risk assessment will be classified into one of four exposure categories: 1) high risk; 2) some risk of exposure; 3) low (but not zero) risk; and 4) no identifiable risk. Health care facility / provider and public health actions to be taken will be based on the exposure category, clinical criteria, and other factors. Details regarding exposure category definitions and actions to be taken are provided in Appendix 2.

Monitoring and Restricted Movement

For persons with potential exposure to EVD, monitoring for EVD symptoms with daily follow-up and reporting to the local health department or KDHE may be indicated. Restricted movement may also be indicated for some individuals. Persons undergoing public health monitoring shall be given information about EVD and an instruction sheet for self-monitoring (Appendix 3).

Active monitoring will entail self-monitoring for fever and other potential symptoms of Ebola virus infection twice per day until 21 days since last potential exposure, with the requirement of

daily public health follow-up via telephone or other means of regular communication. For direct active monitoring, a public health worker from the local health department or KDHE will directly observe the individual at least once daily to review symptoms and monitor temperature measurement. It is recommended that an initial visit by a public health worker be conducted in person early in the direct active monitoring process to help build rapport. This initial visit should be preceded by a telephone call to ensure the individual is well and is not experiencing any symptoms of EVD. Subsequent visits throughout the 21-day period may be conducted via videoconference at the discretion of the local health department or KDHE. The information from the monitoring process shall be recorded on a log sheet (Appendix 3). The public health monitoring process will help to ensure compliance with self-monitoring, assess and identify symptoms early, reduce risks of transmission if the individual develops EVD, and to address any potential concerns.

Asymptomatic persons classified as having either a high-risk exposure or at some risk of exposure within the preceding 21 days will undergo direct active monitoring. Persons with no symptoms in the low (but not zero) risk and no identifiable risk categories will undergo active monitoring. However, in-person, direct active monitoring may be indicated in some circumstances for these individuals as determined by the local health officer or KDHE.

Although the potential risk of exposure to Ebola virus for public health workers conducting in-person, direct active monitoring would be low, public health workers should minimize any potential exposure by maintaining a distance of at least three feet from the person under monitoring and avoiding any direct, hands-on patient care.

Most persons in the high risk exposure and some risk of exposure categories will be subjected to restricted movement and will be requested to remain at their residence or other living location as determined by KDHE or the local health officer for a period of 21 days following their last potential exposure; any movement outside the residence or other living location must be approved in advance by KDHE or the local health officer on a case-by-case basis. During this 21-day period of restricted movement, there shall be no visitors to the residence or living location except those approved by KDHE or the local health officer in advance.

Local health departments and other agencies should develop local plans to ensure basic needs of those persons whose movement is restricted are met. Such needs likely include food and other household necessities, etc.

Failure to comply with the provisions of active monitoring or restricted movement may result in the issuance of more restrictive quarantine orders pursuant to K.S.A. 65-119, K.S.A. 65-128 and K.A.R. 28-1-5.

Most persons in the low (but not zero) risk category shall also be subjected to active monitoring, but the only restrictions regarding travel will be the requirement to notify the local health officer or KDHE before any overnight travel outside the state of Kansas. This requirement is in place to ensure appropriate notification to other states and coordination of the active monitoring process. U.S.-based health care workers caring for Ebola patients while wearing appropriate personal protective equipment (as indicated in Appendix 4) and travelers on an aircraft with, and sitting

within three feet of, a person with Ebola virus disease will be subjected to direct active monitoring.

Any person undergoing either active monitoring or self-monitoring who develops a fever (≥ 38.0°C / 100.4°F **OR** subjective history of fever) ***or other symptoms of EVD*** shall immediately contact their local health department or the **KDHE Epidemiology Hotline at 877-427-7317**. If such persons contact a health care provider or local health department worker first, then the health care provider or local health department worker shall have the responsibility for contacting KDHE. A KDHE Epidemiologist is on call 24 hours per day. The on-call Epidemiologist shall assess self-reported symptoms to determine appropriate public health actions.

Special Considerations for Health Care Workers and Other Potential Occupational Exposure to Ebola Virus

United States-based health care workers, broadly defined as any person working in a health care setting (including laboratory workers and emergency responders), and other workers who are potentially exposed to Ebola virus while caring for a patient with EVD or during environmental cleanup activities will be subject to the same requirements for active monitoring and restricted movement as any other person, with the following exceptions.

Workers who utilize appropriate personal protective equipment (PPE) as detailed in Appendix 4 will be exempt from the 21-day restricted movement period that begins after their last contact with the patient or potentially infectious materials. These workers will be subjected to direct active monitoring and the requirement to notify the local health officer or KDHE before any overnight travel outside the state of Kansas for 21 days after last potential exposure. However, if the employee reports or is observed by a PPE trained observer to have experienced a needle stick or breach in PPE protocol, the full 21-day restricted movement period will apply.

Health care workers potentially exposed to Ebola virus who do not utilize the appropriate level of PPE during patient care will be subjected to direct active monitoring and restricted movement, depending on a risk assessment until 21 days after the last known potential exposure. The risk assessment will include consideration of whether or not the patient was exhibiting vomiting, diarrhea, or obvious bleeding which would increase the risk of transmission of Ebola virus.

Evaluation and Management of Suspected EVD Cases: Information for Health Care Providers, Emergency Medical Services Personnel, and Public Health Officials

It is important to consider that infectious diseases can be acquired and carried by travelers to, or from, any destination in the world. Assessing a patient's travel history is a critical step to understanding how to best address a patient's chief concerns and health issues. An active dialogue between patients and clinicians to accurately assess travel experiences and exposures can be vital to the understanding of many conditions. Diseases occurring at any given time in geographic locations around the world vary greatly and are continuously changing, so keeping up to date with disease trends and knowing where to look for information can be vital. The CDC's Traveler's Health Website (http://wwwnc.cdc.gov/travel) and "Yellow Book" (http://wwwnc.cdc.gov/travel/page/yellowbook-home) provide current information on current situations in other countries. In addition, KDHE has developed an information campaign to encourage a comprehensive approach to increasing awareness of global infectious disease threats. Additional information is available at http://www.kdheks.gov/epi/thinktravelhistory.htm (including downloadable posters) and on Twitter or Facebook by searching #ThinkTravelHistory.

Patients with recent travel (i.e., within the previous 21 days) from countries with current outbreaks or local transmission of EVD who present with fever are more likely to have other potentially serious infectious diseases that should be considered in the differential diagnoses – including but not limited to malaria, typhoid fever, viral respiratory infections, and bacterial infections such as pneumonia – than they are to have EVD.

However, effective patient and public health management require prompt reporting of any potential EVD case to KDHE.

Report all suspect EVD cases within four (4) hours to the KDHE Epidemiology Hotline:

877-427-7317

State-designated Centers of Excellence for Infectious Disease Preparedness and Frontline Hospitals

All hospitals in Kansas have an important responsibility regarding preparedness for infectious diseases, including Ebola virus and other high-consequence pathogens. As part of the domestic Ebola virus preparedness and response effort, the CDC has developed a framework for a tiered approach for hospitals in the U.S. Full details are available at http://www.cdc.gov/vhf/ebola/healthcare-us/preparing/hospitals.html. In this framework, hospitals can serve one of three roles:

- Frontline healthcare facilities
- Ebola assessment hospitals
- Ebola treatment centers

Most hospitals in the U.S. and in Kansas are considered as frontline healthcare facilities. Briefly, frontline hospitals should be able to rapidly identify and triage patients with relevant exposure history and signs or symptoms compatible with EVD, appropriately isolate and manage such patients using appropriate PPE and other infection prevention protocols, notify KDHE of suspect case, and initiate appropriate testing (including for other, more common acute conditions consistent with the signs and symptoms for patients in the low risk category).

As part of the Hospital Preparedness Program Ebola virus cooperative agreement, state health departments are required to designate at least one hospital in the state capable of serving as an Ebola assessment hospital. KDHE engaged regional hospital preparedness coordinators in a planning process to consider the best designation strategy for Kansas. Through this consensus process, it was determined that Kansas would best be served by one designated hospital in each of the Kansas City and Wichita metropolitan areas, respectively. With the recognition that hospital preparedness for high-consequence infectious diseases encompasses much more than Ebola virus, KDHE has designated two hospitals in Kansas as *Centers of Excellence for Infectious Disease Preparedness:*

The University of Kansas Hospital	**Via Christi Hospital St. Francis**
3901 Rainbow Blvd.	929 St Francis N
Kansas City, KS 66160	Wichita, KS 67214

Through a self-assessment process and discussions with KDHE staff, each of the designated hospitals has demonstrated a high degree of preparedness for managing and caring for patients with suspected Ebola virus disease and other high consequence infectious pathogens. In addition, the designated hospitals will engage in intensive planning, exercising, and training activities to enhance their preparedness capabilities.

Persons under public health monitoring who develop symptoms consistent with EVD will be managed according to their exposure risk category and clinical signs and symptoms as indicated in Appendix 2. In general, persons in the "Low (but not zero) Risk" exposure category who are clinically stable and do not have bleeding, vomiting, or diarrhea will be encouraged to seek care at the local hospital of their choice, which in some cases may be frontline healthcare facilities.

Patients who are experiencing bleeding, vomiting, or diarrhea or who are in higher exposure risk categories will be encouraged to seek care at a designated Center of Excellence for Infectious Disease Preparedness or, depending on geographic factors, a designated Ebola Assessment Hospital in a neighboring state. Any such action will depend on the circumstances and will be closely coordinated between the patient, local health department, state health department(s), and designated hospital.

Coordination of patient care at must take into consideration several factors, including the wishes of the patient. All hospitals should be familiar with the KDHE Ebola Virus Disease Preparedness and Response plan (this document), the CDC tiered framework for hospitals, and requirements under the Emergency Medical Treatment and Labor Act (EMTALA). The U.S. Centers for Medicare and Medicaid Services (CMS) and implications for EVD. See attached CMS memorandum dated 21 November 2014 as Appendix 9.

Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Virus Disease in U.S. Hospitals

In this guidance health care personnel (HCP) refers to all persons, paid and unpaid, working in health care settings who have the potential for exposure to patients or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or aerosols generated during certain medical procedures. HCP include, but are not limited to, first responders, physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, morticians, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual personnel, home health care personnel, and persons not directly involved in patient care (e.g., clerical, dietary, house-keeping, laundry, security, maintenance, billing, chaplains, and volunteers) but potentially exposed to infectious agents that can be transmitted to and from HCP and patients. However, there are special considerations for outpatient settings as provided below. This guidance is not intended to apply to persons outside of health care settings.

All persons entering the hospital room of a patient with suspected or confirmed Ebola should adhere to the PPE guidance as detailed in Appendix 4.

As new information becomes available, these recommendations will be re-evaluated and updated as needed. These recommendations are based upon the most current information available and the following considerations:

- High rate of morbidity and mortality among infected patients
- Risk of human-to-human transmission
- Lack of FDA-approved vaccine and therapeutics

If a patient in a Kansas health care facility is suspected or known to have EVD, health care facilities should:

- Isolate the patient: Patients should be isolated in a single patient room (containing a private bathroom whenever possible) with the door closed.
- Wear appropriate PPE as recommended in Appendix 4, including the use of a trained observer.
- Restrict visitors: Avoid entry of visitors into the patient's room. Exceptions may be considered on a case-by-case basis for those who are essential for the patient's wellbeing. Ensure that visitors wear appropriate PPE. A logbook should be kept to document all persons entering the patient's room. See CDC's infection control guidance on procedures for monitoring, managing, and training of visitors.
- Avoid aerosol-generating procedures: If performing these procedures is necessary, they should be performed in an airborne infection isolation room.
- Implement environmental infection control measures: Diligent environmental cleaning and disinfection and safe handling of potentially contaminated materials are of paramount importance, as blood, sweat, vomit, feces, urine, and other body secretions represent potentially infectious materials and should be handled following hospital protocols.

Additional guidance and information can be found in Appendix 4, including a one-page guide for PPE.

Transport of Patients with Suspected or Confirmed Ebola Virus Disease

KDHE has entered into an agreement with the Major Emergency Response Group (MERGe), which is a state resource operated by the Region III EMS Council. As part of this group, the Sedgwick County EMS Biosafety Transport Team provides safe transport of patients with serious infectious diseases, including Ebola virus disease. The team is comprised of three different groups: the transport group, a decontamination group, and safety officers to ensure isolation procedures are properly followed.

In the event an EVD case in Kansas (confirmed or strongly suspected) is identified and needs to be transported, KDHE will authorize such transfer on a case by case basis. Additional details are provided in Appendix 8.

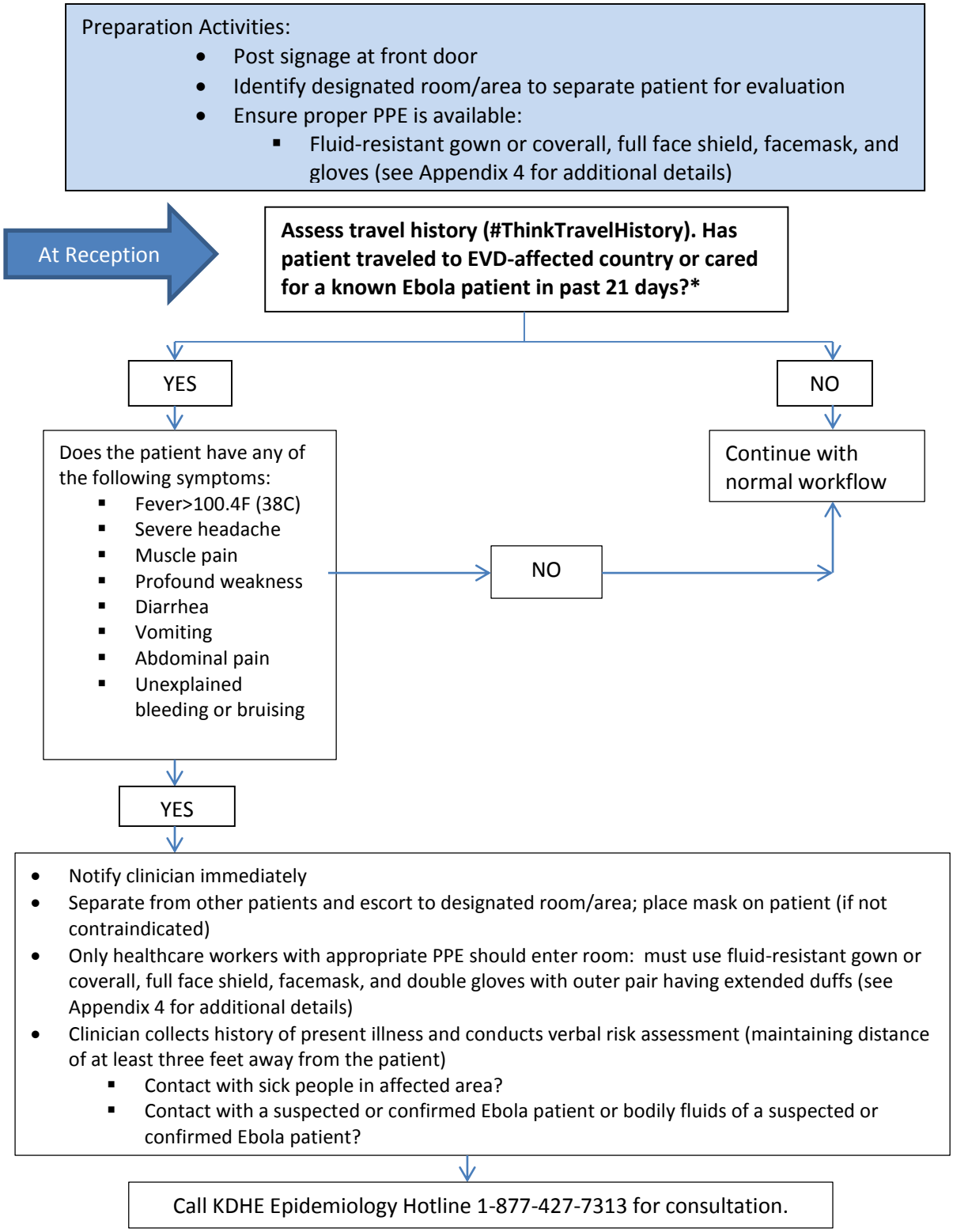
Special Considerations for Outpatient Settings

Patients with suspected Ebola virus disease (i.e., those with pertinent travel history and symptoms consistent with EVD) should be immediately given a surgical mask to don (if tolerated and not medically contraindicated), placed in an isolation gown and isolated in a private patient room. If feasible, facilities should consider utilizing a bathroom for this purpose to facilitate environmental cleaning and decontamination. A chair or two can be placed in the bathroom for the patient to sit; however, if they are ill and require lying down, the facility should identify the best room to do this and prevent other staff/visitors from entering until the final disposition of the patient is determined.

Health care workers in outpatient settings should minimize potential exposure to a patient with suspected EVD by maintaining a distance of at least three feet from patient and avoiding provision of direct, hands-on patient care. If direct patient care is required until the patient is transferred, a single staff member who is trained in proper donning and doffing of PPE should be designated to interact with the patient. The appropriate level of PPE should be utilized as designated in Appendix 4.

Suspected EVD patients should be transported to an appropriate referral hospital in the private vehicle they arrived in with law enforcement escort, if feasible. The outpatient clinic should first notify the referral hospital prior to transporting the patient and make arrangements to be called to confirm the patient arrived. A flowchart for evaluating suspected Ebola virus disease patients is presented in Figure 2.

Figure 2: KDHE Interim Guidelines for Evaluation of Suspected EVD Patients at Outpatient Clinic and Physician's Offices



* http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html#areas

Laboratory Testing

Timeline of Infection	Diagnostic tests available
Within a few days after symptoms begin	▪ Antigen-capture enzyme-linked immunosorbent assay (ELISA) testing ▪ IgM ELISA ▪ Polymerase chain reaction (PCR) ▪ Virus isolation
Later in disease course or after recovery	▪ IgM and IgG antibodies
Retrospectively in deceased patients	▪ Immunohistochemistry testing ▪ PCR ▪ Virus isolation

Notification and consultation

Hospitals should contact KDHE (Epidemiology Hotline: 877-427-7317) for notification and consultation for Ebola testing requests before contacting the CDC. The CDC cannot accept any specimens without prior consultations with KDHE.

Specimen collection

Ebola is detected in the blood only after the onset of symptoms (may take up to three days). Specimens should be collected when a symptomatic patient reports to a health care facility and is suspected of having an Ebola virus exposure. If the onset of symptoms is less than three days, a subsequent specimen may be needed to rule out Ebola virus if the first specimen tests negative. A minimum volume of four milliliters of whole blood preserved with EDTA is preferred, but whole blood preserved with sodium polyanethol sulfonate (SPS), citrate, or clot activator can be submitted for Ebola testing. Specimens should be shipped at 2-8 degrees C on cold packs. Do not freeze specimens (differs from CDC guidance as we are concerned a specimen that is frozen but cycles from frozen to thawed may not render an accurate test result). Do not submit glass containers. Do not submit specimens preserved in heparin tubes.

Packing and shipping specimens for Ebola virus testing

Specimens collected for Ebola virus disease testing should be packaged and shipped without opening collection tubes or aliquot specimens. Specimens for shipment should be packaged following the basic triple packaging system, which consists of a primary container (a sealable specimen bag) wrapped with absorbent material, secondary container (watertight, leak-proof), and an outer shipping package. See Appendix 5 for packaging guidance. Persons responsible for packing and shipping any specimen for Ebola testing should be trained to ship Category A infectious substances. Contact the KDHE Epidemiology Hotline for required submission documents and additional shipping guidance.

Note: In most cases, KDHE anticipates advising submitting laboratories to send specimens directly to the CDC rather than to the Kansas Health and Environmental Laboratories (KHEL). This will be managed on a case-by-case basis.

Transporting specimens within the hospital / institution

In compliance with 29 CFR 1910.1030, specimens should be placed in a durable, leak-proof secondary container for transport within a facility. To reduce the risk of breakage or leaks, do not use any pneumatic tube system for transporting suspected Ebola virus disease specimens.

Centers for Disease Control and Prevention Guidelines

The CDC published its latest guidelines regarding managing and testing routine clinical specimens when there is a concern about EVD in March, 2015. This guidance stresses that the likelihood of EVD is very low among travelers returning from affected countries and consideration of EVD should not delay diagnostic assessments, laboratory testing, and appropriate care for other, more likely medical conditions. The CDC guidance also includes information regarding the appropriate selection of laboratory equipment, including considerations for point of care testing. Companion CDC guidance regarding collection, transport, and submission of specimens for Ebola virus testing was updated in January, 2015. These documents are available at http://www.cdc.gov/vhf/ebola/healthcare-us/laboratories/index.html and are also included as Appendix 6. KDHE is replacing its previous guidance from the American Society for Microbiology with the more recent CDC guidance.

Public Health Management of Suspected EVD Cases

Pursuant to K.S.A. 65-118 and K.A.R. 28-1-2, Ebola virus is considered a "…disease unusual in incidence or behavior…" [as delineated in K.A.R. 28-1-2(a)(52)] and suspected cases of Ebola virus disease must be reported to KDHE by telephone within four (4) hours (Epidemiology Hotline: 877-427-7317). The KDHE-BEPHI will work with the local health department to immediately initiate case and contact investigations so public health measures to prevent potential transmission of Ebola virus can be implemented.

As noted above, KDHE-BEPHI has a detailed Disease Investigation Guideline (DIG) for viral hemorrhagic fever that should be utilized by KDHE and local health department staff (www.kdheks.gov/epi/Investigation_Guidelines/VHF_Disease_Investigation_Guideline.pdf).

Persons with suspected EVD shall be managed as described in the "Management of Persons Potentially Exposed to Ebola Virus and Suspected EVD Cases" section of this document. There are no specific Kansas regulations related to isolation of persons with EVD or quarantine of persons exposed to Ebola virus. Therefore, the provisions of K.A.R. 28-1-5, which specifies that the secretary of Kansas Department of Health and Environment or the local health officer shall order and enforce isolation and quarantine based on current medical knowledge of the particular infectious agent, apply. Statutory authority is provided in K.S.A. 65-101, 65-119, 65-128, and 65-202.

Persons in Kansas who have potential exposures to Ebola virus from a patient with EVD in Kansas or elsewhere in the United States shall be managed in a similar manner as those persons potentially exposed to Ebola virus in other countries; however, contact investigations and associated risk assessments shall be the responsibility of KDHE or the local health department.

Environmental Infection Control

Although risk factors for environmental transmission of Ebola virus are not well understood, there is limited evidence from laboratory studies that Ebola virus can remain viable on solid surfaces under certain environmental conditions for several days. According to the CDC, there is no epidemiologic evidence of environmental Ebola virus transmission via fomites (e.g., bed rails, door knobs, laundry, etc.). However, environmental infection control measures are prudent given the low infectious dose, the potential of high virus titers in blood (and other bodily fluids like vomitus and stool) of ill patients, and the severity of EVD.

There is likely to be considerable amounts of medical waste generated during the course of providing care for a patient with EVD and other waste generated during environmental cleaning and disinfection in health care settings and in community settings.

The U.S. Department of Transportation (DOT) has classified Ebola virus as a Category A infectious substance per its Hazardous Materials Regulations (HMR, 49 C.F.R., Parts 171-180). Any item transported offsite for disposal that is contaminated or suspected of being contaminated with a Category A infectious substance must be packaged and transported in accordance with the HMR. This includes medical equipment, sharps, linens, and used health care products (such as soiled absorbent pads or dressings, kidney-shaped emesis pans, portable toilets, used personal protection equipment (gowns, masks, gloves, goggles, face shields, respirators, booties, etc.) or byproducts of cleaning) contaminated or suspected of being contaminated with a Category A infectious substance.

On 06 October 2014, KDHE issued a written policy pursuant to K.S.A. 65-3430(e)(1)(B) and K.S.A. 65-101(a)(2) and (5) that defines Ebola virus and other hemorrhagic fever viruses as hazardous waste.

KDHE is basing this guidance regarding the treatment, storage, and disposal of Ebola waste based upon guidance and requirements established by KDHE and the World Health Organization, the CDC, and the DOT.

For the purposes of this document, Ebola waste means any untreated medical waste generated in the care of patients with known or suspected Ebola virus disease (EVD) including, but not limited to, medical equipment, sharps, linens, and used health care products, used PPE, and all absorbent or uncleanable items contaminated or potentially contaminated by a suspected EVD patient. Ebola waste is a Category A infectious substance and a Resource Conservation and Recovery Act (RCRA) hazardous waste in the State of Kansas. A RCRA hazardous waste must be transported by a registered hazardous waste transporter and disposed of at a permitted hazardous waste facility (an incinerator).

Ebola waste that has been treated (sterilized) by the generator using effective (autoclaving) procedures may be managed as other Category B Regulated Medical Waste (RMW) in accordance with state and federal transportation and disposal requirements. Such waste may be treated in permitted medical waste disposal facilities. Chemical treatment alone does not remove

the Ebola waste (Category A) designation, nor does it eliminate the hazardous waste classification.

Hospitals and Other Medical Facilities

Hospitals or other medical facilities that have the capability to sterilize Ebola waste in an on-site autoclave should do so as waste is generated to avoid the accumulation of large volumes of untreated Ebola waste on-site. Prior to sterilization in an autoclave, any confirmed or suspect Ebola waste must be properly packaged and labeled while held in temporary storage (see storage requirements below).

Hospitals or other medical facilities without autoclaving capabilities should package the waste following DOT requirements (Title 49, Part 173.196, and other associated DOT guidance). The packaged waste should be properly labeled and placed into secure storage. As soon as such waste handling processes are initiated, the facility should contact KDHE to obtain assistance in identifying and selecting a waste transporter and disposal facility.

Human body fluids from a patient in isolation should be collected for disposal as Ebola waste or collected and treated with 1 part of household bleach to 9 parts water for at least 10 minutes or longer prior to discharge to the sanitary sewer. Facilities should discuss preferred concentrations and treatment time for bodily fluid wastes utilizing this method with their Public Waste Water Treatment facility director and local emergency manager.

Toilet bowls should be primed with a 9:1 (water:bleach) solution prior to introduction of any wastes (i.e., prior to patient use) to ensure wastes voided during toilet equilibrium actions are appropriately treated. Body fluids expelled directly from the patient into a toilet must be treated again with 1 part of household bleach to 9 parts water for at least 10 minutes prior to discharge to the sanitary sewer; this will require consideration of the toilet bowl water volume to ensure a 9:1 (water:bleach) solution is achieved during treatment.

Onsite Storage of Ebola Waste - The DOT shipping packaging adequately satisfies the hazardous waste packaging requirement for untreated Ebola waste. It is recommended that the outer packaging be rigid plastic 55-gallon drums or larger over-pack plastic drums. These containers are capable of being incinerated with the contained waste. All DOT labeling requirements can be included on the “Hazardous Waste” label which must also include the date that the container was placed into storage (there is a 90-day storage time limit). The DOT “Infectious Substance” label should also be adhered to the outer package. The labeling information includes the following: DOT shipping name - "Infectious substances, affecting humans (Ebola Hazardous Waste)", hazardous class/division 6.2 (DOT), DOT ID # UN2814. The hazardous waste code is “EBOLA” to be put into the waste code section of the uniform hazardous waste manifest.

Autoclave Guidelines for Sterilization of Ebola Waste – If the facility uses an autoclave to sterilize the Ebola waste; they should include the following in their procedure to ensure effectiveness:

- All waste should be in biohazard autoclave bags and should be no more than three-fourths full.

- Bags should be tied loosely and about 50 mL of water added to each bag.
- Tape a biological indicator ampoule to the outside of the bag and place bag in a metal autoclave pan or tray. (Note that effectiveness is increased with metal trays.)
- A chemical indicator strip may also be used near the mouth of the bag.
- Autoclave contents for a minimum of 60 min, at 121°C, and 15psi, with slow exhaust.
- The Autoclave log should document the contents, duration, time, pressure, and temperature for the autoclave cycle.
- Document that the chemical indicator strip indicates a successful run. If the chemical indicator fails, then the sterilization should be repeated with fresh indicator. (The chemical indicator provides an initial evaluation of run success. The biological indicator provides confirmation and should be included in every run of the autoclave.)
- Label the bag with the date and time of run or other tracking system that corresponds with the biological indicator ampoule, autoclave log and chemical indicator for that run.
- Hold labeled autoclaved waste until the biological ampoule indicates successful sterilization. (NOTE: The biological indicator must be incubated according to manufacturer's directions for 48 hours to confirm effectiveness of the autoclave to inactivate organisms.)
- Once successful sterilization has been confirmed with the biological indicator, document that bags associated with that run are ready for storage and disposal as Category B Regulated Medical Waste.

NOTES:

Sterilization indicator tape is not equivalent to the biological indicator and chemical strip indicator described above.

The chemical indicators and biological indicators should be used with every autoclave run and their location within the autoclave varied to ensure uniform sterilization throughout the autoclave.

Do not overfill the bags, the secondary containers, or the autoclave itself. Steam must be able to penetrate all areas of the waste material to ensure effectiveness of the sterilization.

Disposal of Ebola Waste – If the facility does not already have a hazardous waste generator ID, KDHE can provide a special ID to allow the waste to be shipped off-site using a uniform hazardous waste manifest. This manifest satisfies both the hazardous waste and DOT shipping paper requirements. KDHE will work with the facility to identify a waste transporter and permitted incineration facility.

Other Generators of Ebola Waste

All other generators of Ebola waste should follow the same packaging and labeling procedures as hospitals that do not have treatment (sterilization) capabilities. Clean-up contractors should coordinate storage and disposal procedures with KDHE. Movement to a temporary secure storage area may be approved by KDHE, if necessary, pending the selection of a permitted disposal facility. Direct loading and transfer to a disposal facility is preferred if this can be pre-arranged.

Handling of Bulky Contaminated Items

Some contaminated or potentially contaminated items that cannot be appropriately cleaned and disinfected may be large and unable to be treated in an autoclave or packed into the approved DOT shipping containers without size reduction. Items may include things such as bedding, chairs, mattresses, etc. It will be necessary to reduce the size of such items using mechanical procedures. The surfaces of these items must first be treated with a U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant with a label claim for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus) or a 9:1 (water:bleach) solution). Note: 9:1 (water:bleach) solution is caustic. Avoid direct contact with skin and eyes. Prepare the bleach solutions in a well-ventilated area. Care must be taken to avoid exposures and the additional spread of contamination during these steps.

All items being prepared for delayed on-site treatment or off-site shipments must be placed in rigid containers that are no larger than 55-gallon drums or larger over-pack containers.

Special DOT Permits

If a disposal facility requires outer packaging that differs from the DOT requirements in Part 173.196, a Special Permit may be requested.

Community Environmental / Decontamination Issues

Local health departments and other local agencies are advised to discuss and plan for how local resources will be identified and utilized to address any potential needs for environmental decontamination of a confirmed case-patient's residence or other structures. Such resources might include local or regional hazardous materials response teams or private contractors. These units are primarily present to isolate a threat and monitor the environmental decontamination and not for clean-up. KDHE is working to develop a resource guide to environmental clean-up organizations familiar with proper PPE and handling of potentially infected blood and fluids. Refer to Environmental Infection Control section above for information on management of waste generated from cleanup activities.

A one-page waste management guide is available in Appendix 7.

Handling of Human Remains of Ebola Virus Disease Patients

The CDC has issued "Guidance for Safe Handling of Human Remains of Ebola Patients in U. S. Hospitals and Mortuaries" (available at http://www.cdc.gov/vhf/ebola/hcp/guidance-safe-handling-human-remains-ebola-patients-us-hospitals-mortuaries.html). KDHE has reviewed the CDC guidance and is adopting it by reference.

Management of Animals Exposed to Ebola Virus

The ongoing epidemic of Ebola in West Africa has raised several questions about how the disease affects the animal population, and in particular, the risk to household pets[1]. While the information available suggests that the virus may be found in several kinds of animals, the CDC, the US Department of Agriculture (USDA), and the American Veterinary Medical Association (AVMA) do not believe that pets are at significant risk for Ebola in the United States[1].

The following guidance is provided to manage animals exposed to the Ebola virus. This guidance will be updated as new information is made available by the CDC, USDA, and AVMA.

Exposure Defined As:
An animal will be considered exposed if it has been in direct contact with a person with confirmed Ebola virus infection from the onset of symptoms of the disease in the person.

Quarantine and Handling Procedures:
The animal will be quarantined for a minimum of 21 days. The following management procedures will be observed:

1. The animal will be quarantined in the residence of the patient with confirmed Ebola virus disease. The animal should be confined to the home and only allowed outside to urinate or defecate. When outside, the animal will be kept on a leash. Solid waste should be removed and disposed of in a waste receptacle. The waste can be disposed of through regular trash removal.
2. Humans who are household contacts of the confirmed Ebola patient, and who live in the residence of the patient, should care for the animal contact(s). Exposure to the animal should be minimized. If the patient does not have another caregiver for the animal, it will be quarantined at an alternate location determined by KDHE or the local health officer.
3. Monitor the animal daily for changes in behavior or health for 21 days following the last potential exposure.
    a. Potential signs of illness include decreased appetite, lethargy, vomiting, and diarrhea.
    b. Report any change in behavior or health immediately to KDHE at 1-877-427-7317.
    c. The animal will be evaluated by a veterinarian to determine the cause of illness. If the veterinarian cannot rule out Ebola virus infection, KDHE will then consult with the CDC for diagnostic recommendations.

Release of Animal from Quarantine:
The animal will be released from quarantine after 21 days, or more, as long as the animal appears clinically normal. There are currently no approved diagnostic tests for pets for Ebola virus infection; therefore, testing is not recommended at this time. Final disposition of the animal will be determined by the Kansas Animal Health Commissioner and the Secretary of KDHE.

References

1. Centers for Disease Control and Prevention. *Questions and Answers about Ebola and Pets.* Accessed on October 15, 2014 at; http://www.cdc.gov/vhf/ebola/transmission/qas-pets.html.
2. Allela, L., Bourry, O., Pouillot, R., et al. *Ebola Virus Antibody Prevalence in Dogs and Human Risk.* Emerging Infectious Diseases. 2005: 11(3); 385-390.

Additional Information

For additional information, refer to the CDC Ebola web page (available from www.cdc.gov) or contact the KDHE Epidemiology Hotline at 877-427-7317.

Appendix 1

Risk Assessment for Individuals Returning from Ebola Affected Areas

An ongoing outbreak of Ebola in West Africa has prompted the need for careful evaluation and management of individuals returning from outbreak affected areas (map available at http://www.who.int/csr/disease/ebola/evd-outbreak.jpg). Entry screening of all passengers is being conducted at the five US airports for all passengers arriving from the affected countries. Risk Assessments should be performed for all individuals identified who have been in the affected areas in the past 21 days.

Demographics

Name (last, first): _____
Address (mailing): _____

Address (physical):_____

City/State/Zip: _____

Phone (home): _____ **Phone** (work/cell): _____

Alternate contact: □*Parent/Guardian* □*Spouse* □*Other*

Name: _____Phone: _____

Birth date: __ / __ / ____ **Age**: _____ **Sex**: ☐Male ☐Female ☐Unknown

Travel History

Were you in a country were an Ebola outbreak is occurring within the last 21 days? ☐Yes ☐No

If yes please continue the assessment, if no then the person was not considered exposed.

List the cities, countries, travel dates and reason for travel while the person was in West Africa

City	Country	Arrival Date	Departure Date	Reason for Travel

Exposures

Ask the person the following exposure questions.

1. Did you come into contact with blood or other body fluids of a person with Ebola while the person was symptomatic? □Yes □No

   If yes, did the contact include any of the following?
   (**YES to any of these = HIGH RISK**)

   a. Stuck with a needle or other sharp object □Yes □No
   b. Splashed in the eye, nose, or mouth? □Yes □No
   c. Blood or other body fluids directly on your skin? □Yes □No

2. Did you provide direct care to anyone with Ebola while that person was symptomatic or enter an area where Ebola patient care was taking place? This includes household or healthcare settings. □Yes □No

   a. **If yes**, document setting:

      □Household member providing care (**HIGH RISK**)

      OR

      □Healthcare worker

   b. For healthcare worker: did you wear appropriate personal protective equipment (PPE) (KDHE Tier 1 level of PPE as described in Appendix 4) at all times?

      □Yes □No

      NO (to appropriate PPE use) = HISH RISK
      YES (to appropriate PPE use) = SOME RISK

3. Did you work in a laboratory in any country processing body fluids of a person with Ebola?

   □Yes □No

   If Yes, did you wear appropriate personal protective equipment (PPE) as described in Appendix 4 and follow standard biosafety precautions at all times? □Yes □No

   - **NO (to appropriate PPE use and standard biosafety precautions) = HISH RISK**
   - **YES (to appropriate PPE use and biosafety precautions) in laboratories deemed by CDC to <u>not have</u> appropriate biosafety precautions in place = SOME RISK**
   - **YES (to appropriate PPE use and biosafety precautions) in laboratories deemed by CDC <u>to have</u> appropriate biosafety precautions in place = LOW RISK**

4. Did you have direct contact with a dead body, have contact with water used to wash dead bodies, or the cloth that covered a dead body? in a country with widespread transmission or cases in a country with widespread transmission or cases in urban

settings with uncertain control measures (http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html)? ☐Yes ☐No

If YES, did you wear appropriate personal protective equipment (PPE) as described in Appendix 4 at all times? ☐Yes ☐No

NO (to appropriate PPE use) = HISH RISK
YES (to appropriate PPE use) = SOME RISK

5. Did you provide direct patient care to persons without Ebola in a country with widespread transmission or cases in urban settings with uncertain control measures (http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html)? ☐Yes ☐No

   YES = SOME RISK

6. Did you spend any time in the same room with any person with Ebola while the person was symptomatic?

   ☐Yes ☐No

   If YES: Were you wearing appropriate personal protective equipment (PPE) as described in Appendix 4 at all times? ☐Yes ☐No

   YES = LOW (BUT NOT ZERO)

   If NO: Ask the following questions:

   a. Did you have any direct contact with the person with Ebola (e.g. shaking hands)? ☐Yes ☐No
      i. What was the stage of illness?
         ☐ Early = **LOW (BUT NOT ZERO)** ☐Late (SEVERLY ILL) = **HIGH RISK**
   b. Were you within 3 feet (1 meter) of a person with Ebola for an extended period of time? ☐Yes ☐No

      YES = SOME RISK NO=LOW (BUT NOT ZERO)

   c. Did you have any other contact with a person with Ebola? ☐Yes ☐No
      Describe contact: _____
      Consult with KDHE to determine risk level

7. Did individual travel on an aircraft with a person with Ebola while the person was symptomatic? ☐Yes ☐No

8. **Personal protective equipment: For health care workers, please provide details regarding the PPE utilized while caring for patients with known or suspected Ebola virus disease:**

   a. Suit / body protection:
      i. ☐ Impermeable gown
      ii. ☐ Impermeable coverall
      iii. ☐ Other (describe):_____
   b. Gloves

i. ☐Single
ii. ☐Double

c. Respiratory protection (check all that apply)
   i. ☐Powered Air Purifying Respirator (PAPR) with a full face shield, helmet, or headpiece, with attached HEPA filter
   ii. ☐N95 respirator
   iii. ☐Surgical mask

d. Face protection
   i. ☐PAPR with full face shield, helmet, or headpiece, with attached HEPA filter
   ii. ☐Full face shield
   iii. ☐Goggles

e. Head cover
   i. ☐PAPR with full face shield, helmet, or headpiece, with attached HEPA filter
   ii. ☐Surgical hood

f. Footwear
   i. ☐Latex or rubber boot
   ii. ☐Impermeable boot covers that extend to mid-calf

EXPOSURE ASSESSMENT:

☐ High Risk ☐Some Risk ☐Low (But Not Zero) ☐No Identifiable Risk

Medical Information

1. Were you ill within the past month during your time in West Africa? ☐Yes ☐No
   a. If so, were you seen by a physician or did you visit a health care facility in West Africa? ☐Yes ☐No
   b. Name of facility: _____ Location of facility: _____
   c. What date did your symptoms begin? __/___/____
   d. What was your diagnosis? _____
   e. Did you have any of the following symptoms?

Fever	☐Yes ☐No
Significant headaches	☐Yes ☐No
Joint or muscle aches	☐Yes ☐No
Nausea or vomiting	☐Yes ☐No
Diarrhea	☐Yes ☐No
Abdominal pains	☐Yes ☐No
Unexplained hemorrhage or bleeding	☐Yes ☐No

2. Have you been ill since your arrival in the United States? ☐Yes ☐No
   a. Is yes what date did your symptoms begin? __/___/____

   b. Did you have any of the following symptoms?

Fever	☐Yes ☐No
What date did your fever develop?	___/___/_____
What was the highest recorded temperature?	
Significant headaches	☐Yes ☐No
Joint or muscle aches	☐Yes ☐No
Nausea or vomiting	☐Yes ☐No
Diarrhea	☐Yes ☐No
Abdominal pains	☐Yes ☐No
Unexplained hemorrhage or bleeding	☐Yes ☐No

3. Have you consulted your personal physician? ☐Yes ☐No
   c. If yes, did he or she order any lab tests? ☐Yes ☐No
   d. May we have his/her name and phone number? _____
      _____
4. Have your symptoms resolved? ☐Yes ☐No
5. What date did your symptoms resolve? __/___/____
6. When was your last influenza immunization? __/___/____
7. Malaria chemoprophylaxis
   a. Were you prescribed medication to take while travelling to prevent malaria? ☐Yes ☐No
   b. If yes, did you take all medication as prescribed? ☐Yes ☐No

Hospital Planning

If you develop a fever or other symptoms of Ebola virus disease during your 21-day monitoring period, what is your preferred hospital?

Name: _____

City / State:_____

Appendix 2

Interim Guidance for Evaluation and Management of Persons with Potential Ebola Virus Disease Exposure

Exposure Level	Clinical Criteria	Health Care Facility and Public Health Actions
High Risk In any country • Percutaneous (e.g., needle stick) or mucous membrane exposure to blood or body fluids (including but not limited to feces, saliva, sweat, urine, vomit, and semen[1]) from a person with Ebola who has symptoms • Direct contact with a person with Ebola who has symptoms, or the person's body fluids, **while not wearing appropriate personal protective equipment (PPE)** • Laboratory processing of blood or body fluids from a person with Ebola who has symptoms **while not wearing appropriate PPE or without using standard biosafety precautions** • Providing direct care to a person showing symptoms of Ebola in a household setting In countries with widespread transmission or cases in urban settings with uncertain control measures • Direct contact with a dead body **while not wearing appropriate PPE.**	Fever (subjective or measured as ≥100.4 degrees F or 38.0 degrees C) OR other symptoms consistent with EVD: • Severe headache • Muscle pain • Vomiting • Diarrhea • Stomach pain • Unexplained bruising or bleeding	• Consideration as a probable case (http://www.cdc.gov/vhf/ebola/hcp/case-definition.html#probable) • Medical evaluation using infection control precautions (Appendix 4) for suspected Ebola, consultation with KDHE (Epidemiology Hotline: 877-427-7317), and testing if indicated ○ Patients in the "High Risk Exposure" category will be encouraged to seek care at one of Kansas's two designated Centers of Excellence for Infectious Disease Preparedness • The University of Kansas Hospital (Kansas City, KS) • Via Christi Hospital St. Francis (Wichita, KS) ○ Depending on geographic location of patient, care at a designated Ebola Assessment Hospital in a neighboring state may be indicated • If air transport is clinically appropriate and indicated, only air medical transport (http://www.cdc.gov/vhf/ebola/hcp/guidance-air-medical-transport-patients.html) (no travel on commercial conveyances permitted) • If infection control precautions are determined not to be indicated: direct active monitoring and restricted movement until 21 days after last known potential exposure
	Asymptomatic	• Direct active monitoring • Restricted movement until 21 days after last known potential exposure
Some Risk of Exposure In any country • Being in close contact[2] with a person with Ebola who has symptoms **while not wearing appropriate PPE** (for example, in households, healthcare facilities, or community settings) • *In non-U.S. laboratories that CDC has not deemed as having appropriate biosafety precautions in place,* laboratory	Fever (subjective or measured as ≥100.4 degrees F or 38.0 degrees C) OR other symptoms consistent with EVD: • Severe headache • Muscle pain • Vomiting • Diarrhea • Stomach pain • Unexplained bruising or bleeding	• Consideration as a probable case (http://www.cdc.gov/vhf/ebola/hcp/case-definition.html#probable) • Medical evaluation using infection control precautions (Appendix 4) for suspected Ebola, consultation with KDHE (Epidemiology Hotline: 877-427-7317), and testing if indicated ○ Patients in the "Some Risk of Exposure" category will be encouraged to seek care at one of Kansas's two designated Centers of Excellence for Infectious Disease Preparedness • The University of Kansas Hospital (Kansas City, KS) • Via Christi Hospital St. Francis (Wichita, KS)

<table>
<tr>
<td rowspan="2">processing of blood or body fluids from a person with Ebola who has symptoms while wearing appropriate PPE and using standard biosafety precautions
○ Assessment of laboratory facility will be conducted on returning travelers by CDC Division of Global Migration and Quarantine

<u>In countries with widespread transmission</u>
• Direct contact with a person with Ebola who has symptoms, or the person's body fluids, while wearing appropriate PPE
• Being in the patient-care area of an Ebola treatment unit
• Providing any direct patient care in non-Ebola healthcare settings</td>
<td></td>
<td>○ Depending on geographic location of patient, care at a designated Ebola Assessment Hospital in a neighboring state may be indicated
• If air transport is clinically appropriate and indicated, only air medical transport (http://www.cdc.gov/vhf/ebola/hcp/guidance-air-medical-transport-patients.html) (no travel on commercial conveyances permitted)
• If infection control precautions are determined not to be indicated: active monitoring and restricted movement until 21 days after last known potential exposure</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>• Direct active monitoring
• Restricted movement until 21 days after last known potential exposure
• Special considerations for U.S.-based health care workers caring for EVD patients
○ Health care workers who utilize the appropriate level of personal protective equipment (PPE) as detailed in Appendix 4 will be exempt from the 21-day restricted movement period
○ Health care workers potentially exposed to Ebola virus who do not utilize the appropriate level of PPE or who experience a breach in infection prevention protocols will be subjected to restricted movement, dependent on a risk assessment, until 21 days after the last known potential exposure.</td>
</tr>
<tr>
<td>Low (but not zero) risk

<u>In any country</u>
• Brief direct contact (such as shaking hands) with a person in the early stages of Ebola, while not wearing appropriate PPE. Early signs can include fever, fatigue, or headache.
• Brief proximity with a person with Ebola who has symptoms (such as being in the same room, but not in close contact) while not wearing appropriate PPE
• In non U.S. laboratories that CDC has deemed as having appropriate biosafety precautions in place, laboratory processing of blood or body fluids from a person with Ebola who has symptoms while wearing appropriate PPE and using standard biosafety precautions
○ Assessment of laboratory facility will be conducted on returning travelers by CDC Division of</td>
<td>Fever (subjective or measured as <u>≥</u>100.4 degrees F or 38.0 degrees C) OR other symptoms consistent with EVD:
• Severe headache
• Muscle pain
• Vomiting
• Diarrhea
• Stomach pain
• Unexplained bruising or bleeding</td>
<td>• Consideration as a probable case (http://www.cdc.gov/vhf/ebola/hcp/case-definition.html#probable)
• Medical evaluation using infection control precautions (Appendix 4) for suspected Ebola, consultation with KDHE (Epidemiology Hotline: 877-427-7317), and testing if indicated
○ Patients in the "Low (but not zero) Risk" category who are clinically stable and do not have bleeding, vomiting, or diarrhea will be encouraged to seek care at the local hospital of their choice
○ Patients in the "Low (but not zero) Risk" category who are clinically unstable or who have bleeding, vomiting, or diarrhea will be encouraged to seek care at one of Kansas's two designated Centers of Excellence for Infectious Disease Preparedness
• The University of Kansas Hospital (Kansas City, KS)
• Via Christi Hospital St. Francis (Wichita, KS)
○ Depending on geographic location of patient, care at a designated Ebola Assessment Hospital in a neighboring state may be indicated
• If air transport is clinically appropriate and indicated, only air medical transport (http://www.cdc.gov/vhf/ebola/hcp/guidance-air-medical-transport-patients.html) (no travel on commercial conveyances permitted)</td>
</tr>
</table>

Global Migration and Quarantine • Traveling on an airplane with a person with Ebola who has symptoms and having had no identified *some* or *high* risk exposures <u>In countries with widespread transmission, cases in urban settings with uncertain control measures, or former widespread transmission and current, established control measures</u> • Having been in one of these countries and having had no known exposures <u>In any country other than those with widespread transmission</u> • Direct contact with a person with Ebola who has symptoms, or the person's body fluids, while wearing appropriate PPE • Being in the patient-care area of an Ebola treatment unit		• If infection control precautions are determined not to be indicated: active monitoring and restricted movement until 21 days after last known potential exposure
	Asymptomatic	• Direct active monitoring for: ○ U.S.-based health care workers caring for symptomatic Ebola patients while wearing appropriate PPE as described in Appendix 4 ○ Travelers on an aircraft with, and sitting within 3 feet of, a person with Ebola • Active monitoring until 21 days after leaving country for all others in this category • No movement restrictions except the requirement to notify the local health officer or KDHE before any overnight travel outside the state of Kansas for 21 days after last potential exposure.
No identifiable risk • Laboratory processing of Ebola-containing specimens in a Biosafety Level 4 facility • Any contact with a person who isn't showing symptoms of Ebola, even if the person had potential exposure to Ebola virus • Contact with a person with Ebola before the person developed symptoms • Any potential exposure to Ebola virus that occurred **more than 21 days previously** • Having been in a country with Ebola cases, but **without** widespread transmission, cases in urban settings with uncertain control measures, or former widespread transmission and now established control measures, and not having had any other exposures	Symptomatic (any)	• Routine medical evaluation and management of ill persons, as needed
	Asymptomatic	• No actions needed

• Having stayed on or very close to an airplane or ship (for example, to inspect the outside of the ship or plane or to load or unload supplies) during the entire time that the airplane or ship was in a country with widespread transmission or a country with cases in urban settings with uncertain control measures, **and** having had no direct contact with anyone from the community • Having had laboratory-confirmed Ebola and subsequently been determined by public health authorities to no longer be infectious (i.e., Ebola survivors)		

[1] Ebola virus can be detected in semen for months after recovery from the disease. Unprotected contact with the semen of a person who has recently recovered from Ebola may constitute a potential risk for exposure. The period of risk is not yet defined.

[2] Close contact is defined as being within approximately 3 feet (1 meter) of a person with Ebola while the person was symptomatic for a prolonged period of time while not using appropriate PPE.

Definitions

Close contact – Close contact is defined as being within approximately 3 feet (1 meter) of a person with Ebola while the person was symptomatic for a prolonged period of time while not using appropriate PPE.

Active and Direct Active Monitoring – Active monitoring will entail self-monitoring for fever and other potential symptoms of Ebola virus infection twice per day until 21 days since last potential exposure, with the requirement of daily public health follow-up via telephone or other means of regular communication. For direct active monitoring, a public health worker from the local health department or KDHE will directly observe the individual at least once daily to review symptoms and monitor temperature measurement. It is recommended that an initial visit by a public health worker be conducted in person early in the direct active monitoring process to help build rapport. This initial visit should be preceded by a telephone call to ensure the individual is well and is not experiencing any symptoms of EVD. Subsequent visits throughout the 21-day period may be conducted via videoconference at the discretion of the local health department or KDHE. The information from the monitoring process shall be recorded on a log sheet (Appendix 3). The public health monitoring process will help to ensure compliance with self-monitoring, assess and identify symptoms early, reduce risks of transmission if the individual develops EVD, and to discuss any potential concerns.

Restricted movement – Persons must remain at their residence or other living location as determined by KDHE or the local health officer for a period of 21 days following their last potential exposure; any movement outside the residence or other living location must be approved in advance by KDHE or the local health officer on a case-by-case basis. During this 21-day period of restricted movement, there shall be no visitors to the residence or living location except those approved by KDHE or the local health officer in advance.

Special Considerations for Health Care Workers – Health care workers, broadly defined as any person working in a health care setting (including laboratory workers and emergency responders), and other workers who are potentially exposed to Ebola virus while caring for a patient with EVD or during environmental cleanup activities will be subject to the same requirements for active monitoring and restricted movement as any other person, with the following exceptions.

Workers who utilize appropriate personal protective equipment (PPE) as detailed in Appendix 4 will be exempt from the 21-day restricted movement period that begins after their last contact with the patient or potentially infectious materials. These workers will be subjected to direct active monitoring and the requirement to notify the local health officer or KDHE before any overnight travel outside the state of Kansas for 21 days after last potential exposure. However, if the employee reports or is observed by a PPE trained observer to have experienced a needle stick or breach in PPE protocol, the full 21-day restricted movement period will apply.

Appendix 3

Guidance for Persons Traveling from the West African nations of Guinea or Sierra Leone to Kansas

This is guidance for persons who have traveled to Guinea or Sierra Leone within the past 21 days and are now returning to Kansas.

Symptoms of EVD typically include an abrupt onset of fever, headache, joint and muscle aches, weakness, diarrhea, vomiting, stomach pain, and loss of appetite. Some patients may also experience a rash, red eyes, hiccups, cough, sore throat, chest pain, difficulty breathing, difficulty swallowing, and bleeding inside and outside of the body. The typical incubation period (time between exposure and onset of symptoms) is eight to 10 days, though the range is two to 21 days.

Ebola virus can be transmitted from person-to-person by:

- Direct contact with the blood or body fluids of an infected person
- Exposure to objects (such as needles) that have been contaminated with blood or other body fluids from an infected person

Ebola virus is **not** transmitted from person-to-person through the air, water, or food.

If you returned within the previous 21 days from Guinea or Sierra Leone; have had any of the following high or low risk exposures; have a fever (subjective or measured as $\geq$100.4°F or 38.0°C) and additional symptoms such as severe headache, muscle pain, vomiting, diarrhea, abdominal pain, or unexplained hemorrhage, call the Kansas Department of Health and Environment (KDHE) at 877-427-7317 and your local hospital's emergency department if needed prior to seeking care.

Check your temperature twice daily and monitor for other signs and symptoms of EVD for 21 days after your exposure. Use the medical monitoring log on the next page. If you develop fever and other symptoms of EVD within 21 days of your exposure, call the KDHE Epidemiology Hotline at 877-427-7317. KDHE or the local health department will make ***daily*** contact with you to discuss and document temperature, symptoms, and to discuss any concerns.

DAILY MEDICAL MONITORING LOG:

Monitor yourself for fever twice daily for 21 days after returning from an Ebola-affected country. Mark the date, time you took your temperature (mark whether it was AM or PM), and temperature. If you develop a fever (either feeling feverish or measured as ≥100.4°F or 38.0°C) note the other symptoms you are experiencing and immediately call your local health department or the Kansas Department of Health and Environment's Epidemiology Hotline at 877-427-7317.

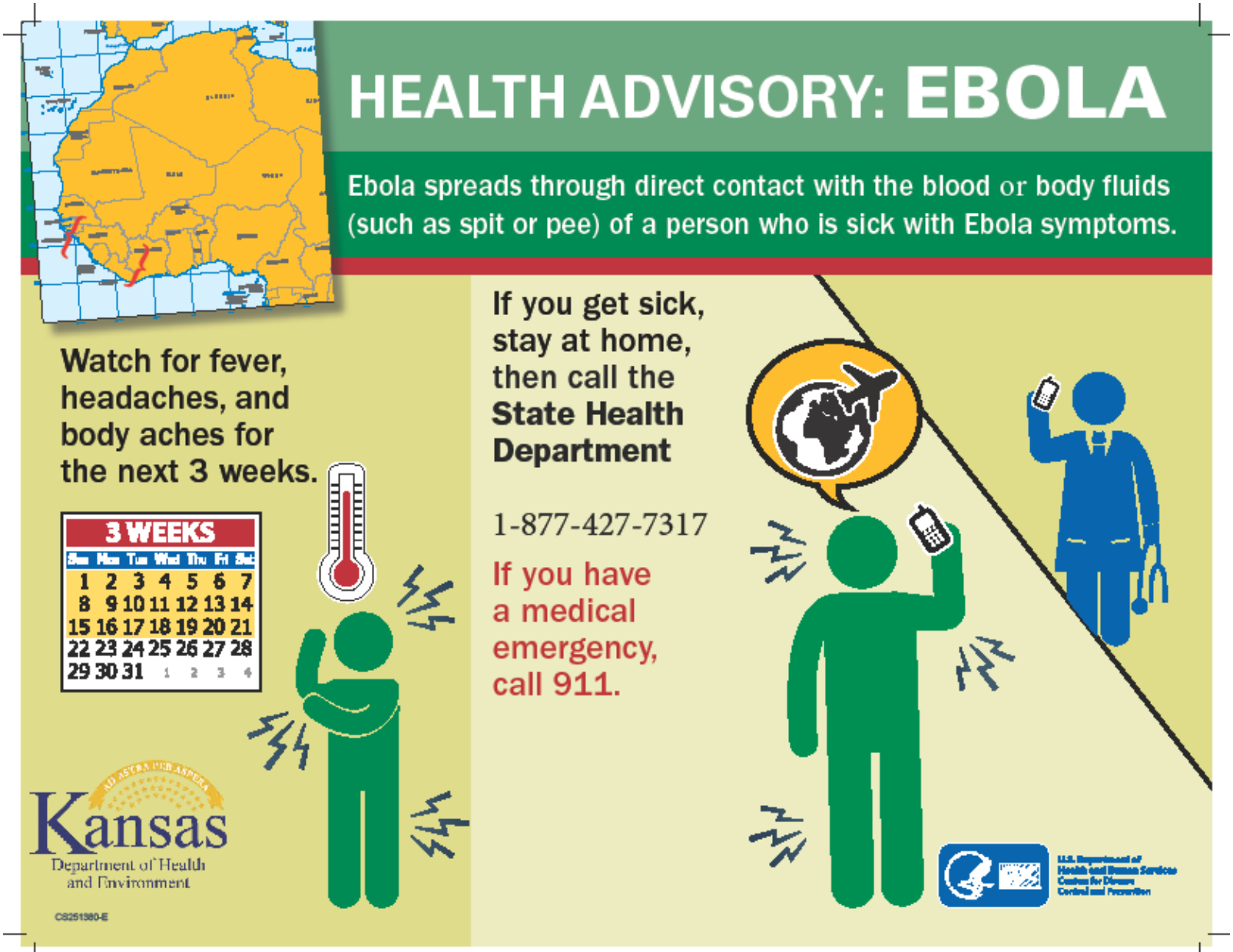
Day	Date	Time Taken	Temperature
1		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
2		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
3		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
4		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
5		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
6		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
7		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
8		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
9		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
10		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
11		_____□AM□PM	_____°F
		_____□AM□PM	_____°F

Day	Date	Time Taken	Temperature
12		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
13		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
14		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
15		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
16		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
17		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
18		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
19		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
20		_____□AM□PM	_____°F
		_____□AM□PM	_____°F
21		_____□AM□PM	_____°F
		_____□AM□PM	_____°F

If you have developed a fever please check the boxes of any symptoms you are experiencing.

□ Headache □Joint or Muscle Aches □Weakness □Vomiting □Diarrhea □ Stomach or Abdominal Pain □ Lack of Appetite

□Cough □ Sore throat □Rash □Shortness of Breath □Chest Pain


HEALTH ADVISORY: EBOLA
Ebola spreads through direct contact with the blood or body fluids (such as spit or pee) of a person who is sick with Ebola symptoms.
Watch for fever, headaches, and body aches for the next 3 weeks.
3 WEEKS
If you get sick, stay at home, then call the State Health Department
1-877-427-7317
If you have a medical emergency, call 911.
Kansas
Department of Health and Environment
CS251380-E

Take your temperature two times a day, morning and night.

- This thermometer is for YOU ONLY.
- Please DO NOT SHARE it.

- KEEP IT for yourself for the next 21 days.

DO NOT take your temperature right after eating or drinking.

1. Turn the thermometer on. It will show an "L" in the screen when it is ready.

2. Hold the tip under your tongue for 60 seconds until it beeps

3. Read the temperature

4. Write your temperature on the chart you got at the airport. or from the local health department.

If your temperature is 100.4°F / 38°C or higher or you are sick, call the State Health Department 1-877-427-7317.
If you have a medical emergency, call 911.

5. You can clean your thermometer with soap and water.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Kansas
Department of Health and Environment

Appendix 4: Personal Protective Equipment (PPE) Guidelines

Centers for Disease Control and Prevention

For U.S. Healthcare Settings: Donning and Doffing Personal Protective Equipment (PPE) for Evaluating Persons Under Investigation (PUIs) for Ebola Who Are Clinically Stable and Do Not Have Bleeding, Vomiting, or Diarrhea

Page Summary

Who this is for: Healthcare providers in the U.S. evaluating PUIs for Ebola who are clinically stable AND do not have bleeding, vomiting, or diarrhea

What this is for: Provides guidance on the processes for donning and doffing PPE for healthcare workers and staff who are evaluating a PUI who is clinically stable and does not have bleeding, vomiting, or diarrhea

How to use this, how it relates to other guidance documents: Use this guidance with frontline (http://www.cdc.gov/vhf/ebola/hcp/preparing-frontline-healthcare-facilities.html) and assessment (http://www.cdc.gov/vhf/ebola/hcp/preparing-ebola-assessment-hospitals.html) healthcare facilities described in Interim Guidance for U.S. Hospital Preparedness for Patients Under Investigation (PUIs) or with Confirmed Ebola Virus Disease (EVD): A Framework for a Tiered Approach (http://www.cdc.gov/vhf/ebola/hcp/us-hospital-preparedness.html). It offers step-by-step processes for donning and doffing PPE described in Identify, Isolate, Inform: Emergency Department Evaluation and Management for Patients Under Investigation (PUIs) for Ebola Virus Disease *(EVD)*. These procedures do NOT apply to healthcare workers caring for patients with confirmed Ebola or to healthcare workers caring for PUIs who have bleeding, vomiting, diarrhea, or who are clinically unstable and/or will require invasive or aerosol-generating procedures (e.g., intubation, suctioning, active resuscitation). In those cases, use the Guidance on Personal Protective Equipment (PPE) To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE.

Recommended PPE:

While evaluating and managing PUIs who are clinically stable and do not have bleeding, vomiting, or diarrhea, healthcare providers should at a minimum wear:

- Single-use (disposable) fluid-resistant gown that extends to at least mid-calf or single-use (disposable) fluid-resistant coveralls without integrated hood
- Single-use (disposable) full face shield
- Single-use (disposable) facemask
- Single-use (disposable) gloves with extended cuffs. Two pairs of gloves should be worn. At a minimum, outer gloves should have extended cuffs.

In this guidance, fluid-resistant means a gown that has demonstrated resistance to water or a coverall that has demonstrated resistance to water or synthetic blood. The specific test methods that assess resistance are listed in Table 1. When purchasing gowns and coveralls, facilities should follow specifications in this table to ensure they select recommended gowns and coveralls.

Table 1. Specifications for fluid-resistant gowns and coveralls

	Gown	Coverall
Fluid-resistant	Surgical or isolation* gown that passes: • ANSI/AAMI PB70 Level 3 requirements or • EN 13795 high performance surgical gown	Coverall* made of fabric that passes: • AATCC 42 ≤ 1 g and AATCC 127 ≥ 50 cm H_2O or EN 20811 ≥ 50 cm H_2O or • ASTM F1670 (13.8kPa) or • ISO 16603 ≥ 3.5 kPa

*Testing by an ISO 17025 certified third party laboratory is **recommended**

For more details, refer to technical document Considerations for Selecting Protective Clothing used in Healthcare for Protection against Microorganisms in Blood and Body Fluids, which provides a more detailed explanation of the scientific evidence and national and international standards, test methods, and specifications for fluid-resistant and impermeable protective clothing used in health care settings.

Facilities should ensure that healthcare providers are trained and able to demonstrate competency in donning and doffing recommended PPE before being allowed to care for PUIs. Facilities should also designate areas for PPE donning and doffing as specified below (for more information, refer to the Guidance on Personal Protective Equipment (PPE) To Be Used By Healthcare Workers during

Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE.

- Ensure that areas for donning and doffing are separate from the patient care area (e.g., patient's room) and that there is a predominantly one-way flow of movement of healthcare providers from the donning area to the patient care area or room to the doffing area.
- Confirm that the doffing area is large enough to allow freedom of movement for safe doffing, has space for waste (http://www.cdc.gov/vhf/ebola/hcp/medical-waste-management.html) containers, a new glove supply, and alcohol-based hand rub (ABHR) for use during the doffing process.

Donning PPE

Donning PPE – This donning procedure applies to PPE recommended for evaluating and managing PUIs who are clinically stable and do not have bleeding, vomiting, or diarrhea. There is a lower risk of splashes and contamination in these situations. An established protocol, combined with proper training of the healthcare worker (HCW), helps to facilitate compliance with PPE guidance.

1. **Remove Personal Clothing and Items**: The HCW should wear surgical scrubs (or disposable garments) and dedicated washable (plastic or rubber) footwear. No personal items (e.g., jewelry [including rings], watches, cell phones, pagers, pens) should be worn under PPE or brought into the patient room. Long hair should be tied back. Eye glasses should be secured with a tie.
2. **Inspect PPE Prior to Donning**: Visually inspect the PPE ensemble to ensure that it is in serviceable condition (e.g., not torn or ripped), that all required PPE and supplies are available, and that the sizes selected are correct for the HCW.
3. **Perform Hand Hygiene**: Perform hand hygiene with alcohol-based hand rub (ABHR). When using ABHR, allow hands to dry before moving to next step.
4. **Put on Inner Gloves**: Put on first pair of gloves.
5. **Put on Gown *or* Coverall**: Put on gown *or* coverall. Ensure gown *or* coverall is large enough to allow unrestricted movement. Ensure cuffs of inner gloves are tucked under the sleeve of the gown *or* coverall.
6. **Put on Facemask**: Put on facemask.
7. **Put on Outer Gloves**: Put on second pair of gloves (with extended cuffs). Ensure the cuffs are pulled over the sleeves of the gown *or* coverall.
8. **Put on Face Shield**: Put on full face shield over the surgical facemask to protect the eyes, as well as the front and sides of the face.
9. **Verify**: After completing the donning process, the integrity of the ensemble should be verified by the HCW (e.g., there should be no cuts or tears in the PPE). The HCW should be comfortable and able to extend the arms, bend at the waist, and go through a range of motions to ensure there is

sufficient range of movement while all areas of the body remain covered. A mirror in the room can be useful for the HCW while donning PPE.

Doffing PPE

Doffing PPE – PPE is doffed in the designated PPE removal area in the healthcare facility. As with all PPE doffing, meticulous care should be taken to avoid self-contamination. Place all PPE waste in a leak-proof infectious waste container.

1. **Inspect**: Inspect the PPE for visible contamination, cuts, or tears before starting to remove. If any PPE is visibly contaminated, disinfect by using an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html). If the facility conditions permit and appropriate regulations are followed, an *EPA-registered disinfectant spray can be used, particularly on contaminated areas.
2. **Disinfect and Remove Outer Gloves**: Disinfect outer-gloved hands with either an *EPA-registered disinfectant wipe or ABHR. Remove and discard outer gloves, taking care not to contaminate inner gloves when removing the outer gloves. Dispose of outer gloves into the designated leak-proof infectious waste container.
3. **Inspect and Disinfect Inner Gloves**: Inspect the inner gloves' outer surfaces for visible contamination, cuts, or tears. If an inner glove is visibly soiled, then disinfect the glove with either an *EPA-registered disinfectant wipe or ABHR, remove the inner gloves, perform hand hygiene with ABHR on bare hands, and don a new pair of gloves. If a cut or tear is seen on an inner glove, immediately review occupational exposure risk per hospital protocol. If there is no visible contamination and no cuts or tears on the inner gloves, then disinfect the inner-gloved hands with either an *EPA-registered disinfectant wipe or ABHR.
4. **Remove Face Shield**: Remove the full face shield by tilting the head slightly forward, grabbing the rear strap and pulling it over the head, gently allowing the face shield to fall forward. Avoid touching the front surface of the face shield. Discard the face shield into the designated leak-proof infectious waste container.
5. **Disinfect Inner Gloves**: Disinfect inner gloves with either an *EPA-registered disinfectant wipe or ABHR.
6. **Remove Gown *or* Coverall**: Remove and discard.
   a. Depending on gown design and location of fasteners, the HCW can either untie fasteners or gently break fasteners. Avoid contact of scrubs or disposable garments with outer surface of gown during removal. Pull gown away from body, rolling inside out and touching only the inside of the gown.
   b. To remove coverall, tilt head back to reach zipper or fasteners. Unzip or unfasten coverall completely before rolling down while turning inside out. Avoid contact of scrubs with outer

surface of coverall during removal, touching only the inside of the coverall. Dispose of gown or coverall into the designated leak-proof infectious waste container.

7. **Disinfect and Change Inner Gloves**: Disinfect inner gloves with either an *EPA-registered disinfectant wipe or ABHR.
   a. Remove and discard gloves, taking care not to contaminate bare hands during removal process.
   b. Perform hand hygiene with ABHR.
   c. Don a new pair of inner gloves.
8. **Remove Surgical Facemask**: Remove the surgical facemask by tilting the head slightly forward, grasping first the bottom tie or elastic strap, then the top tie or elastic strap, and remove the front of the surgical facemask without touching it. Discard the surgical face mask into the designated leak-proof infectious waste container.
9. **Disinfect and Remove Inner Gloves**: Disinfect inner-gloved hands with either an *EPA-registered disinfectant wipe or ABHR. Remove and discard gloves, taking care not to contaminate bare hands during removal process. Dispose of inner gloves into the designated leak-proof infectious waste container.
10. **Perform Hand Hygiene**: Perform hand hygiene with ABHR.
11. **Inspect**: The HCW should inspect for any contamination of the surgical scrubs or disposable garments. If there is contamination, shower immediately, and then immediately inform the infection preventionist or occupational safety and health coordinator or their designee.

*EPA-registered disinfectant wipe: Use a disposable wipe impregnated with a U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant with a label claim for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus); see EPA list of Disinfectants for Use Against the Ebola Virus at http://www.epa.gov/oppad001/list-l-ebola-virus.html (http://www.epa.gov/oppad001/list-l-ebola-virus.html).

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National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) (/ncezid/dw-index.html)
Division of High-Consequence Pathogens and Pathology (DHCPP) (/ncezid/dhcpp/index.html)
Viral Special Pathogens Branch (VSPB) (/ncezid/dhcpp/vspb/index.html)

Centers for Disease Control and Prevention

Guidance on Personal Protective Equipment (PPE) To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE

Updated: This guidance is current as of August 27, 2015

Page Summary

Who this is for: Healthcare workers, supervisors, and administrators at U.S. hospitals.

What this is for: To protect healthcare workers and other patients at facilities that provide care to a patient with confirmed Ebola or PUI who is clinically unstable or has bleeding, vomiting, or diarrhea by describing protocols for using PPE.

How to use: Incorporate into infection control and safety training for healthcare workers who provide care to patients with Ebola and use in planning for staffing and supply management.

How it relates to other guidance documents: There are two PPE guidance documents for U.S. hospital workers who may evaluate or care for Ebola patients. Workers should wear this recommended PPE ensemble when evaluating and caring for:

1. A person who meets the definition of a Person Under Investigation (PUI) for Ebola and is
   a. Exhibiting obvious bleeding, vomiting, or diarrhea; OR
   b. Clinically unstable and/or will require invasive or aerosol-generating procedures (e.g., intubation, suctioning, active resuscitation).
2. A person with confirmed Ebola.

Refer to For U.S. Healthcare Settings: Donning and Doffing Personal Protective Equipment (PPE) for Evaluating Persons Under Investigation (PUIs) for Ebola Who Are Clinically Stable and Do Not have Bleeding, Vomiting, or Diarrhea recommended when evaluating and caring for a PUI who is:

1. Not exhibiting obvious bleeding, vomiting, or diarrhea; AND
2. Clinically stable and will not require invasive or aerosol-generating procedures (e.g., intubation, suctioning, active resuscitation).

Key points

- Healthcare workers caring for patients with Ebola must have received comprehensive training and demonstrated competency in performing Ebola-related infection control practices and procedures.
- PPE that covers the clothing and skin and completely protects mucous membranes is required when caring for patients with Ebola.
- Personnel providing care to patients with Ebola must be supervised by an onsite manager at all times, and a trained observer must supervise each step of every PPE donning/doffing procedure to ensure established PPE protocols are completed correctly.
- Individuals unable or unwilling to adhere to infection control and PPE use procedures should not provide care for patients with Ebola.

Updates to previous versions of this guidance

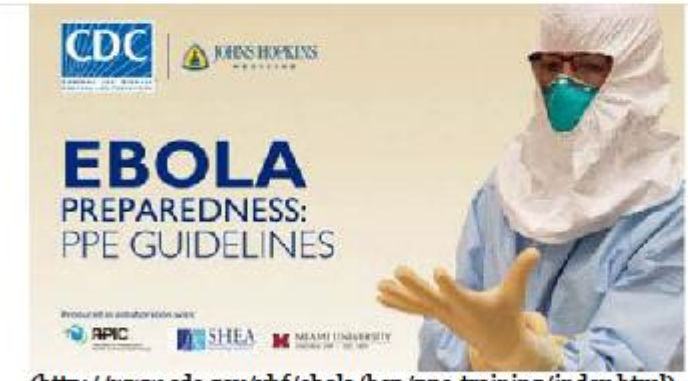
This Ebola PPE guidance has been updated to add detail, clarify where needed, and improve the format. Specifically, the guidance was updated to:

- Expand the rationale for respiratory protection;
- Clarify that the trained observer should not serve as an assistant for doffing PPE;
- Suggest that a designated doffing assistant or "buddy" might be helpful, especially in doffing with the powered air purifying respirator (PAPR) option;
- Modify the PAPR doffing procedure to make the steps clearer;
- Change the order of boot cover removal. Boot covers should now be removed after the gown or coverall;
- Clarify the types of gowns and coveralls that are recommended and provide a link to considerations for gown and coverall selection; and
- Emphasize the importance of frequent cleaning of the floor and work surfaces in the doffing area.

Selecting Protective Clothing
(http://www.cdc.gov/niosh/npptl/topics/protectiveclothing/)

›

Respiratory Protection for Ebola (http://www.youtube.com/watch?v=8y19h1hecgY&feature=youtu.be)



(http://www.cdc.gov/vhf/ebola/hcp/ppe-training/index.html)
Web-based PPE training (http://www.cdc.gov/vhf/ebola/hcp/ppe-training/index.html)

Introduction

The following guidance on the types of PPE to be used and the processes for donning (putting on) and doffing (removing) PPE is for all personnel entering the room of a patient hospitalized with Ebola. This guidance reflects lessons learned from the recent experiences of U.S. hospitals caring for patients with Ebola and emphasizes the importance of **training, practice, competence, and observation** of healthcare workers, especially in correct donning and doffing of PPE.

In healthcare settings, Ebola is spread through direct contact with blood or body fluids of a person who is sick with Ebola or with objects (e.g., bathroom surfaces, medical equipment) that have been contaminated with infectious blood or body fluids. The virus in blood and body fluids can enter a person's body through broken skin or unprotected mucous membranes in, for example, the eyes, nose, or mouth. For all healthcare workers caring for patients with Ebola, PPE that fully covers skin and clothing and prevents any exposure of the eyes, nose, and mouth is recommended to reduce the risk of accidental self-contamination of mucous membranes or broken skin. All PPE must be used in the context of a comprehensive infection control program that follows CDC recommendations and applicable Occupational Safety and Health Act of 1970 (OSHA) requirements, including the Bloodborne Pathogens (29 CFR 1910.1030) (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051), PPE (29 CFR 1910.132) (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=9777), and Respiratory Protection (20 CFR 1910.134) (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=12716) standards, and other requirements under OSHA (e.g., the General Duty Clause, section 5(a)(1); and prohibitions against discrimination or retaliation against workers, section 11(c)).

To protect healthcare workers who are caring for patients with Ebola, healthcare facilities must provide onsite management and oversight of adherence to safely using PPE, and implement administrative and environmental controls with continuous safety checks through direct observation of healthcare workers, including during the PPE donning and doffing steps.

Section 1. Recommended Administrative and Environmental Controls for Healthcare Facilities

Protecting healthcare workers and preventing spread of Ebola to other patients requires that proper administrative procedures and safe work practices be carried out in appropriate physical settings. These include the following:

- At an administrative level, the facility's infection prevention management team (i.e., infection control), in collaboration with the facility's occupational health department and other clinical departments, should:
  - Establish and implement triage protocols to effectively and promptly identify patients who could have Ebola.
  - Designate site managers who are responsible for overseeing the implementation of routine and additional precautions for healthcare worker and patient safety. These site managers should have experience in implementing protocols for employee safety, infection control, and patient safety. A site manager's sole responsibility is to ensure the safe delivery of clinical care to patients with Ebola. They are responsible for all aspects of Ebola infection control, including access to supplies and ongoing evaluation of safe practices with direct observation of care before, during, and after staff enter an isolation and treatment area.
    - At least one site manager should be on-site at all times in the location where a patient with Ebola is receiving care.
    - Consider engaging the hospital incident command structure to further facilitate implementing Ebola-specific precautions.
  - Identify, ahead of time, critical patient care functions and essential healthcare workers to care for patients with Ebola, collect laboratory specimens, and manage the environment and waste.
  - Ensure healthcare workers have been trained and evaluated in all recommended protocols to safely care for patients with Ebola before they enter the patient care area.
  - Ensure that workplace safety programs are in place and have been followed, in particular for OSHA's Bloodborne Pathogens, PPE and Respiratory Protection standards described above. Coordinate with safety program administrators to ensure that all PPE, including respirators, has been selected on the basis of a written risk assessment and that requirements for medical surveillance, medical clearance, fit testing, training, maintenance, storage, reporting, etc. are in place for all workers with potential exposure to Ebola.
  - Train healthcare workers on all PPE recommended in the facility's protocols. Healthcare workers should practice donning and doffing procedures and must demonstrate competency through testing and assessment before caring for patients with Ebola.
  - Healthcare workers should practice simulated patient care activities while wearing the PPE to understand the types of physical stress that might be involved and determine tolerable shift lengths.
    - Use trained observers to make certain that PPE is being used correctly and that donning and doffing PPE protocols are being adhered to by using a checklist for each step of the donning and doffing procedure.

        - Personnel who are unable to correctly use PPE and adhere to protocols should not provide care for patients with Ebola.
    - Document training of observers and healthcare workers for proficiency and competency in donning and doffing PPE and in performing all necessary care-related duties while wearing PPE.
    - Designate spaces so that PPE can be donned and doffed in separate areas to prevent any cross- contamination.
- Key safe work practices include the following:
    - Identify and promptly isolate the patient with Ebola in a single patient room with a closed door and a private bathroom or covered bedside commode.
    - Limit room entry to only those healthcare workers essential to the patient's care and restrict non-essential personnel and visitors from the patient care area.
    - Monitor the patient care area at all times, and, at a minimum, log entry and exit of all healthcare workers who enter the room of a patient with Ebola.
    - Be able to safely conduct routine patient care activities (e.g., obtaining vital signs and conducting clinically- appropriate examinations, collecting and appropriately packaging laboratory specimens).
    - Dedicate a trained observer to watch closely and provide coaching for each donning and each doffing procedure to ensure adherence to donning and doffing protocols.
    - Ensure that healthcare workers take sufficient time to don and doff PPE slowly and correctly without distraction.
    - Reinforce the need to keep hands away from the face during any patient care and to limit touching surfaces and body fluids.
    - Frequently disinfect gloved hands by using an alcohol-based hand rub (ABHR), particularly after contact with body fluids.
    - Prevent needlestick and sharps injuries by adhering to correct sharps handling practices,
        - Avoid unnecessary procedures involving sharps.
        - Use needleless IV systems whenever possible.
    - Immediately clean and disinfect any visibly contaminated PPE surfaces, equipment, or patient care area surfaces using an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html).
    - Regularly clean and disinfect surfaces in the patient care area, even in the absence of visible contamination.
        - Only nurses or physicians should clean and disinfect surfaces in the patient care areas to limit the number of additional healthcare workers who enter the room.

- Observe (by the site manager or his/her designee) healthcare workers in the patient room if possible (e.g., through a glass-walled intensive care unit [ICU] room, video link) to identify any unrecognized lapses or near misses in safe care.
- Establish a facility exposure management plan that addresses decontamination and follow-up of healthcare workers in the case of any unprotected exposure. Training and follow-up should be part of the healthcare worker training.

Section 2. Principles of PPE

Healthcare workers must follow the basic principles below to ensure that no infectious material reaches unprotected skin or mucous membranes while providing patient care.

- Donning
  - PPE must be donned correctly in proper order before entry into the patient care area; PPE should not be later modified while in the patient care area. The donning activities must be directly observed by a trained observer.
- During Patient Care
  - PPE must remain in place and be worn correctly for the duration of work in potentially contaminated areas. PPE should not be adjusted during patient care. In the event of a significant splash, the healthcare worker should immediately move to the doffing area to remove PPE. The one exception is that visibly contaminated outer gloves can be changed while in the patient room and patient care can continue. Contaminated outer gloves can be disposed of in the patient room with other Ebola-associated waste.
  - Healthcare workers should perform frequent disinfection of gloved hands using an ABHR, particularly after contact with body fluids.
  - If during patient care any breach in PPE occurs (e.g., a tear develops in an outer glove, a needlestick occurs, a glove separates from the sleeve), the healthcare worker must move immediately to the doffing area to assess the exposure. The facility exposure management plan should be implemented; including correct supervised doffing and appropriate occupational health follow-up, if indicated by assessment. In the event of a potential exposure, bloodborne pathogen exposure procedures must be followed in accordance with the OSHA Bloodborne Pathogens Standard (https://www.osha.gov/SLTC/healthcarefacilities/standards.html).
- Doffing
  - Removing used PPE is a high-risk process that requires a structured procedure, a trained observer, a doffing assistant in some situations, and a designated area for removal to ensure protection.

- PPE must be removed slowly and deliberately in the correct sequence to reduce the possibility of self-contamination or other exposure to Ebola.
- A stepwise process should be developed and used during training and patient care.

Double-gloving provides an easy way to remove gross contamination by changing an outer glove during patient care and when removing PPE. Beyond this, more layers of PPE may make it more difficult to perform patient care duties and put healthcare workers at greater risk for percutaneous injury (e.g., needlesticks), self-contamination during care or doffing, or other exposures to Ebola. If healthcare facilities decide to add additional PPE or modify this PPE guidance, they must consider the risk/benefit of any modification and train healthcare workers on how to correctly don and doff for the modified procedure. Donning and doffing steps may need to be adapted on the basis of the specific PPE that is purchased by the hospital. If adaptations are made, facilities must select PPE that offers a similar or higher level of protection than what is recommended here, train healthcare workers in its use, and ensure they demonstrate competence in its use before caring for a patient with Ebola.

Section 3. Training on Correct Use of PPE

Training ensures that healthcare workers are knowledgeable and proficient in donning and doffing PPE before caring for a patient with Ebola. Comfort and proficiency when donning and doffing are only achieved by repeatedly practicing correct use of PPE. Healthcare workers should be required to demonstrate competency in using PPE, including donning and doffing while being observed by a trained observer, before working with patients with Ebola. Training should be tailored to the intended audience and effectively transmit the required information. In addition, during practice, healthcare workers and their trainers should assess proficiency and comfort with performing required duties while wearing PPE. People unwilling or unable to fulfill these requirements should not care for a patient with Ebola.

- The following elements are essential for PPE training:
  - How to safely don, adjust, use, and doff the specific PPE that the healthcare worker will use;
  - How to safely conduct routine clinical care;
  - Limitations of the PPE (e.g., duration of use, degree of protection);
  - What to do in the case of an equipment failure or detection of a breach in PPE;
  - How to maintain PPE and appropriately dispose of it after use; and
  - The possible physiologic strain associated with using PPE, and how to recognize and report early signs and symptoms, such as fatigue.
- Training must be interactive and should allow frontline healthcare workers to practice donning, adjusting, using, and doffing the specific PPE that the employee will use.

- Hospitals should ensure that the trained employees understand the content of the training and can correctly perform the required tasks.
- Hospitals should also ensure that employees can demonstrate how to properly don, use, and doff the same type/model PPE and respirators that they will use when caring for a patient.
- Regular refresher trainings are essential to maintaining these skills.

Section 4. Use of a Trained Observer

Because the sequence and actions involved in each donning and doffing step are critical to avoid exposure, a trained observer should read aloud to the healthcare worker each step in the procedure checklist and visually confirm and document that the step has been completed correctly. The trained observer has the sole responsibility of ensuring that donning and doffing processes are adhered to. The trained observer must be knowledgeable about all PPE recommended in the facility's protocol and the correct donning and doffing procedures, including how to dispose of used PPE, and must be qualified to provide guidance and recommendations to the healthcare worker. The trained observer will coach, monitor, and document successful donning and doffing procedures, and provide immediate corrective instruction if the healthcare worker is not following the recommended steps. However, the trained observer should NOT provide physical assistance during doffing, which would require direct contact with potentially contaminated PPE. The trained observer is required to wear PPE, nonetheless, because the coaching role will necessitate being present in the PPE removal area during the doffing process. PPE for the trained observer is described in Section 8. The trained observer should know the exposure management plan in the event of an unintentional break in procedure. A designated doffing assistant or "buddy" might be helpful in some circumstances, e.g., during the doffing of the PAPR.

Section 5. Designating Areas for PPE Donning and Doffing

- Ensure that areas for donning and doffing are designated as separate from the patient care area (e.g., patient's room) and that there is a predominantly one-way flow from the donning area to the patient care area to the doffing area.
- Confirm that the doffing area is large enough to allow freedom of movement for safe doffing as well as space for a waste receptacle, a new glove supply, and ABHR used during the doffing process. If using a PAPR with external belt-mounted blower, confirm that there is an area or container designated for collecting PAPR components for cleaning and disinfection, as well as routine maintenance.

Facilities should ensure that space and layout allow for clear separation between clean and contaminated areas. Separate the space into distinct areas and establish a directional, one-way flow of care, moving from clean areas (e.g., area where PPE is donned and unused equipment is stored) to the patient room and to the PPE removal area (area where potentially contaminated PPE is

removed and discarded). The direction of flow should be marked (e.g., signs on the floor) with visible signage; temporary plastic enclosures can be added if necessary. Existing anterooms to patient rooms have been used for doffing but in many cases are not ideal because of their small dimensions. As an alternative, some steps of the PPE removal process may be performed in a clearly designated area of the patient's room near the door, provided these steps can be seen and supervised by a trained observer (e.g., through a window) and provided that the healthcare worker doffing PPE can hear the instructions of the trained observer.

Whenever possible, close the end of the hallway of a ward or ICU to through traffic, thereby restricting access to the patient's room to essential personnel who are properly trained in recommended infection prevention practices for caring for patients with Ebola. Designate two adjacent rooms, located on either side of the patient's room, to be cleared of equipment and furniture and used as donning and doffing areas. Glass-enclosed rooms or other designs (e.g., wide glass doors, windows, video monitoring) to observe ongoing care in the patient room and activity in the doffing area are preferred. The path from the room of the patient with Ebola to an external doffing room should be as short as possible and clearly defined and/or enclosed as a contaminated area that is cleaned frequently along with the doffing area. If areas are reconfigured, the facility should make certain the space remains compliant with all applicable building and fire codes.

Post signage to highlight key aspects of PPE donning and doffing, including

- Designating clean areas vs. contaminated areas
- Reminding healthcare workers to wait for a trained observer before removing PPE
- Listing each step of the doffing procedure
- Reinforcing the need for slow and deliberate removal of PPE to prevent self-contamination
- Reminding healthcare workers to disinfect gloved hands in between steps of the doffing procedure, as indicated below.

Designate the following areas with appropriate signage

1. PPE Storage and Donning Area

This is a clean area outside the patient room (e.g., a nearby vacant patient room, a marked area in the hallway outside the patient room) where clean PPE is stored and where healthcare workers don PPE before entering the contaminated area and the patient's room. Do not store potentially contaminated equipment (e.g., PAPR components that have not been cleaned and disinfected), used PPE, or waste removed from the patient's room in the clean area. If waste must pass through this area, it must be properly contained.

2. Patient Room

Use a single-patient room, preferably with a private bathroom; a covered bedside commode with bagging of human waste is an alternative approach. Plan ahead for the need to store many bags of regulated medical waste before their secondary containment. Additional guidance on waste management can be accessed at Ebola-Associated Waste Management and www.osha.gov/Publications/OSHA_FS-3766.pdf [PDF - 6 pages] (www.osha.gov/Publications/OSHA_FS-3766.pdf). The door to the patient room should be kept closed. Any item or healthcare worker exiting this room should be considered contaminated.

3. PPE Doffing Area

Designate an area near the patient's room (e.g., anteroom or adjacent vacant patient room that is separate from the clean area) where healthcare workers leaving the patient's room can stand to doff and discard their PPE. Alternatively, some steps of the PPE removal process may be performed in a clearly designated area of the patient's room near the door, provided these steps can be seen and supervised by a trained observer (e.g., through a window and provided that the healthcare worker doffing PPE can hear the instructions of the trained observer). Do not use this designated area within the patient room for any other purpose. Stock gloves in a clean section of the PPE removal area accessible to the healthcare worker while doffing.

In the PPE removal area, provide supplies to disinfect PPE and perform hand hygiene and space to remove PPE, including an easily cleaned and disinfected seat where healthcare workers can remove boot or shoe covers. If space allows, designate stations around the perimeter of the doffing room where each piece of PPE will be removed, moving from more contaminated to less contaminated areas of the room as PPE is doffed. Provide leak-proof disposable infectious waste containers for discarding used PPE. Provide a container to collect all reusable PAPR components. Frequently clean and disinfect the PPE removal area, including after each doffing procedure has been completed. One way such cleaning may be achieved is by having another healthcare worker who has just donned their full PPE clean the doffing area, moving from cleaner to dirtier areas within the doffing area, before entering the patient's room.

Facilities should consider making showers available for use for the comfort of healthcare workers after doffing PPE at the end of their shift; the heat from wearing PPE is likely to cause significant perspiration.

Section 6. Selecting PPE for Healthcare Workers Who Care for Patients with Ebola

This section outlines several PPE combinations and how they should be worn. The key to safely wearing PPE is consistent and correct use reinforced by repeated training and practice. Variations in PPE used to care for patients with Ebola should be avoided within a facility. A facility should

select and standardize the PPE to be used by all healthcare workers who are directly interacting with patients with Ebola. OSHA's Bloodborne Pathogens standard requires employers to establish a written Exposure Control plan designed to eliminate or minimize employee exposures and should include procedures for donning and doffing the PPE ensemble that is chosen. The protocol must be reviewed by staff who participate in Ebola care and the trained observer should ensure the protocol is adhered to.

Airborne transmission of Ebola has not been documented in hospitals or households during any of the human outbreaks investigated to date. However, certain procedures (e.g., bronchoscopy, endotracheal intubation) might create mechanically generated aerosols that could be infectious. Such aerosol-generating procedures require additional precautions. Experience in the care of patients hospitalized with Ebola in the United States indicates that the level of care may change unexpectedly and could require an aerosol-generating procedure. Because there might not be time for staff to leave the room to don proper PPE for an aerosol-generating procedure, CDC recommends that all healthcare workers entering the room of a patient with Ebola wear respiratory protection that would protect them during an aerosol-generating procedure. This would include a NIOSH-certified, fit-tested N-95 or higher respirator, or a PAPR.

Safety and comfort are both critical for healthcare workers wearing PPE while caring for patients with Ebola. Standardized attire under PPE (e.g., surgical scrubs or disposable garments and dedicated washable footwear) helps the donning and doffing process and eliminates concerns of contaminating personal clothing. Footwear should be closed-toe, soft-soled, washable, and have a closed back. If facilities elect to use different PPE from what is outlined below (e.g., coveralls with either an integrated hood or a surgical hood with integrated full face shield), they must train healthcare workers on how to use each type of PPE type and ensure that donning and doffing procedures are adjusted and practiced accordingly. Extra layers of PPE are not advised because they can reduce comfort, field of vision, and mobility and increase the risk of error and injury while adding no meaningful protection for the wearer.

In this guidance, *impermeable* gowns and coveralls indicates that the material and construction have demonstrated resistance to synthetic blood and simulated bloodborne pathogens. In contrast, fluid-resistant indicates a gown that has demonstrated resistance to water or a coverall that has demonstrated resistance to water or synthetic blood. These categories reflect the currently available U.S. product specifications; specific test methods that assess resistance for these products are listed in Table 1. When purchasing gowns and coveralls, facilities should follow specifications in Table 1 to ensure they select gowns and coveralls as described in Sections 5 and 6 below.

Table 1. Specifications for impermeable and fluid-resistant gowns and coveralls

	Gown	Coverall
Impermeable	Surgical or isolation* gown that passes: • ANSI/AAMI PB70 Level 4 requirements	Coverall* made with fabric and seams/closures that passes: • ASTM F1671 (13.8kPa) or • ISO 16604 ≥ 14 kPa
Fluid-resistant	Surgical or isolation* gown that passes: • ANSI/AAMI PB70 Level 3 requirements or • EN 13795 high performance surgical gown requirements	Coverall* made of fabric that passes: • AATCC 42 ≤ 1 g and AATCC 127 ≥ 50 cm H_20 or EN 20811 ≥ 50 cm H_20 or • ASTM F1670 (13.8kPa) or • ISO 16603 ≥ 3.5 kPa

*Testing by an ISO 17025 certified third party laboratory is recommended.

For more details, refer to technical document "Considerations for Selecting Protective Clothing used in Healthcare for Protection Against Microorganisms in Blood and Body Fluids", which provides a more detailed explanation of the scientific evidence and national and international standards, test methods, and specifications for fluid-resistant and impermeable protective clothing used in healthcare (http://www.cdc.gov/niosh/npptl/topics/protectiveclothing/default.html).

Section 7. Recommended PPE When Caring for a Patient with Confirmed Ebola or Unstable PUI

- **Impermeable garment:**
  - **Single-use (disposable) impermeable gown** extending to at least mid-calf.
    OR
  - **Single-use (disposable) impermeable coverall**. Coveralls without integrated hoods are preferred; coveralls with or without integrated socks are acceptable. Coveralls and gowns should be available in appropriate sizes so people with long arms are able to cover their forearms without gaps between gloves and sleeves when extending their arms to perform normal duties. Consider selecting gowns or coveralls with thumb hooks to the secure sleeves over the inner glove. Facilities that choose to tape gloves will need to ensure that the tape does not tear the gloves or gown/coverall during doffing and that sharp implements, such as

scissors, are not needed to remove the tape. Experience in some facilities suggests that taping can increase risk by making the doffing process more difficult and cumbersome; however, other facilities have identified ways to optimize the use of tape and other adherent materials to anchor sleeves over inner gloves. **Scissors should never be used to remove tape or any other part of PPE**.

- **Respiratory Protection:** Either a PAPR or disposable, NIOSH-certified N95 respirator should be worn in case a potentially aerosol-generating procedure needs to performed emergently. PAPRs with a full-face covering and head-shroud make accidental self-contamination during care more difficult (e.g., while adjusting eyeglasses); disposable N95 face piece respirators are less cumbersome and can be easier to doff safely. Any respirator must be used in the context of a comprehensive, written respiratory protection program as required under OSHA Respiratory Protection Standard (https://www.osha.gov/SLTC/healthcarefacilities/standards.html), 29 CFR 1910.134. This standard includes a hazard assessment to ensure appropriate respirator protection, fit testing, medical evaluation, and training of the worker. When required in the occupational setting, tight-fitting respirators cannot be used by people with facial hair that interferes with the face seal.
  - **PAPR**: A hooded respirator with a full face shield, helmet, or headpiece. Any reusable helmet or headpiece must be covered with a single-use (disposable) hood that extends to the shoulders and fully covers the neck and is compatible with the selected PAPR. If a hood is used over the PAPR, it must not interfere with the function of the PAPR. The facility should follow manufacturer's instructions for decontaminating reusable components and, on the basis of those instructions, develop facility protocols that include designating responsible personnel who ensure that the equipment is safely and appropriately reprocessed and that batteries are fully charged before reuse.
    - A PAPR with a self-contained filter and blower unit integrated inside the helmet can facilitate doffing.
    - A PAPR with external belt-mounted blower unit requires an additional doffing step, as described below.
  - **N95 Respirator**: Single-use (disposable) N95 respirator or higher in combination with single-use (disposable) surgical hood extending to shoulders and single-use (disposable) full face shield[1]. If N95 respirators are used instead of PAPRs, healthcare workers should be carefully observed to ensure that they do not inadvertently touch their faces under the face shield during patient care.
- **Single-use (disposable) examination gloves with extended cuffs**. Two pairs of gloves should be worn so that a heavily soiled outer glove can be safely removed and replaced during care. At a minimum, outer gloves should have extended cuffs. Double-gloving also allows potentially contaminated outer gloves to be removed during doffing to avoid self-contamination.

- **Single-use (disposable) boot covers** that extend to at least mid-calf. In addition, single-use (disposable) ankle-high shoe covers ("surgical booties") worn over boot covers may be considered to facilitate the doffing process, reducing contamination of the floor in the doffing area thereby reducing contamination of underlying shoes. Although the use of shoe covers over boot covers may be analogous to using double gloves to ensure safe doffing, the risk of significant contamination to underlying shoes from the floor during the doffing process is very low relative to the risk of gloved hand contamination. Thus facilities may consider methods other than shoe covers worn over boot covers to facilitate doffing of footwear including, most importantly, frequent cleaning of the floor in the doffing area. Boot and shoe covers (if the latter are used) should allow for ease of movement and must not present a slip hazard to the wearer.
  - **Single-use (disposable) shoe covers** are acceptable only if they will be used in combination with a coverall with integrated socks.
- **Single-use (disposable) apron** that covers the torso to the level of the mid-calf should be used over the gown or coveralls if patients with Ebola are vomiting or have diarrhea, and should be used routinely if the facility is using a coverall that has an exposed, unprotected zipper in the front. An apron provides additional protection, reducing the contamination of gowns or coveralls by body fluids and providing a way to quickly remove a soiled outer layer during patient care. Select an apron with a neck strap that can be easily broken or untied to avoid having to pull the strap over the head, which makes it easier to remove without self-contamination when exchanging a soiled apron during care or when removing the apron during the doffing procedure.

Section 8. Recommended PPE for Trained Observer and Doffing Assistant during Observations of PPE Doffing

The trained observer should not enter the room of a patient with Ebola but must be in the PPE donning and doffing area to observe donning and doffing procedures, as outlined in Section 7. The following PPE are recommended for trained observers and doffing assistants observing the doffing process:

- Single-use (disposable) fluid-resistant gown that extends to at least mid-calf or single-use (disposable) fluid-resistant coverall without integrated hood.
- Single-use (disposable) full face shield.
- Single-use (disposable) surgical mask.
- Single-use (disposable) gloves with extended cuffs. Two pairs of gloves should be worn. At a minimum, outer gloves should have extended cuffs.
- Single-use (disposable) ankle-high shoe covers. Shoe covers should allow for ease of movement and not present a slip hazard to the wearer.

Trained observers should don and doff selected PPE according to the same procedures outlined below.

Facilities may elect to use impermeable gowns or coveralls for their trained observers to standardize the PPE in the unit, for ease of training personnel on a single item, and to prevent healthcare personnel entering the patient care area from inadvertently selecting a fluid-resistant gown or coverall instead of the recommended impermeable garment. If facilities elect to use fluid-resistant gowns or coveralls for their trained observers, they must take measures (e.g., staff training, good signage, clear labeling of the product, good inventory management practices) to ensure that the correct garment is selected by appropriate personnel.

Section 9. Recommended Sequences for Donning PPE

Section 9A. Donning PPE, PAPR Option

Donning PPE, PAPR Option – This donning procedure assumes the facility has elected to use PAPRs. An established protocol facilitates training and compliance. A trained observer should verify compliance with the protocol.

1. **Engage Trained Observer:** The donning process is guided and supervised by a trained observer, who confirms visually that all PPE is serviceable and has been donned successfully. The trained observer should use a written checklist to guide and confirm each step in donning PPE and can verify the integrity of the ensemble. No exposed clothing, skin or hair of the healthcare worker should be visible at the conclusion of the donning process.
2. **Remove Personal Clothing and Items:** Change into surgical scrubs (or disposable garments) and dedicated washable (plastic or rubber) footwear in a suitable clean area. No personal items (e.g., jewelry including rings, watches, cell phones, pagers, pens) should be brought into the patient room. Long hair should be tied back. Eye glasses should be secured with a tie.
3. **Inspect PPE Before Donning:** Visually inspect the PPE ensemble to be worn to ensure that it is in serviceable condition, all required PPE and supplies are available, and the sizes selected are correct for the healthcare worker. The trained observer should review the donning sequence with the healthcare worker before the donning process and read it aloud to the healthcare worker in a step-by-step fashion.
4. **Put on Boot Covers:** If a coverall without integrated socks is worn, the upper band of the boot cover will be worn UNDER the pants leg of the coverall to prevent pooling of liquids between the coverall pants leg and upper band of boot cover. This step can be omitted if wearing a coverall with integrated socks.
5. **Put on Inner Gloves:** Put on first pair of gloves.

6. **Put on Gown *or* Coverall:** Put on gown or coverall. Ensure gown or coverall is large enough to allow unrestricted freedom of movement. Ensure cuffs of inner gloves are tucked under the sleeve of the gown *or* coverall.
   a. If a PAPR with a self-contained filter and blower unit that is integrated inside the helmet is used, then the belt and battery unit must be put on before donning the impermeable gown *or* coverall so that the belt and battery unit are contained under the gown *or* coverall.
   b. If a PAPR with external belt-mounted blower is used, then the blower and tubing must be on the outside of gown *or* coverall to ensure proper airflow.
7. **Put on Outer Gloves:** Put on second pair of gloves (with extended cuffs). Ensure the cuffs are pulled over the sleeves of the gown *or* coverall.
8. **Put on Respirator:** Put on PAPR with a full face-shield, helmet, or headpiece.
   a. If a PAPR with a self-contained filter and blower unit integrated inside the helmet is used, then a single-use (disposable) hood that extends to the shoulders and fully covers the neck must also be used. Be sure that the hood covers all of the hair and the ears, and that it extends past the neck to the shoulders.
   b. If a PAPR with external belt-mounted blower unit and attached reusable headpiece is used, then a single-use (disposable) hood that extends to the shoulders and fully covers the neck must also be used. Ensure that the hood covers all of the hair and the ears and it extends past the neck to the shoulders.
9. **Put on Outer Apron (if used):** Put on a disposable apron to provide an additional layer for the front of the body.
10. **Verify:** After completing the donning process, the trained observer should verify the integrity of the ensemble. The healthcare worker should be able to extend the arms, bend at the waist, and go through a range of motion sufficient for patient care delivery while all remaining correctly covered. A mirror in the room can be useful for the healthcare worker while donning PPE.

Section 9B. Donning PPE, N95 Respirator Option

Donning PPE, N95 Respirator Option – This donning procedure assumes the facility has elected to use N95 respirators. An established protocol facilitates training and compliance. Use a trained observer to verify successful compliance with the protocol.

1. **Engage Trained Observer:** The donning process is guided and supervised by a trained observer who confirms visually that all PPE is serviceable and has been donned successfully. The trained observer should use a written checklist to confirm each step in donning PPE and verify the integrity of the ensemble. No exposed clothing, skin or hair of the healthcare worker should be visible at the end of the donning process.
2. **Remove Personal Clothing and Items:** Change into surgical scrubs (or disposable garments) and dedicated washable (plastic or rubber) footwear in a suitable, clean area. No personal items (e.g.,

jewelry including rings, watches, cell phones, pagers, pens) should be brought into patient room. Long hair should be tied back. Eye glasses should be secured with a tie.

3. **Inspect PPE Before Donning**: Visually inspect the PPE ensemble to be worn to ensure it is in serviceable condition, all required PPE and supplies are available, and the sizes selected are correct for the healthcare worker. The trained observer should review the donning sequence with the healthcare worker before donning begins and read it aloud during donning in a step-by-step fashion.
4. **Put on Boot Covers.** If a coverall without integrated socks is worn, the upper band of the boot cover will be worn UNDER the pants leg of the coverall to prevent pooling of liquids between the coverall pants leg and upper band of boot cover. This step can be omitted if wearing a coverall with integrated socks.
5. **Put on Inner Gloves:** Put on first pair of gloves.
6. **Put on Gown or Coverall:** Put on gown *or* coverall. Ensure gown *or* coverall is large enough to allow unrestricted freedom of movement. Ensure cuffs of inner gloves are tucked under the sleeve of the gown *or* coverall.
7. **Put on N95 Respirator:** Put on N95 respirator. Complete a user seal check.
8. **Put on Surgical Hood:** Over the N95 respirator, place a surgical hood that covers all of the hair and the ears, and extends past the neck to the shoulders. Ensure that hood completely covers the ears and neck.
9. **Put on Outer Apron (if used):** Put on a disposable apron to provide an additional layer for the front of the body.
10. **Put on Outer Gloves:** Put on second pair of gloves (with extended cuffs). Ensure the cuffs are pulled over the sleeves of the gown *or* coverall.
11. **Put on Face Shield:** Put on full face shield over the N95 respirator and surgical hood to protect the eyes, as well as front and sides of the face.
12. **Verify:** After completing the donning process, the trained observer should verify the integrity of the ensemble. The healthcare worker should be able to extend the arms, bend at the waist, and go through a range of motion sufficient for patient care delivery while all remaining correctly covered. A mirror in the room can be useful for the healthcare worker while donning PPE.

Preparing for Doffing

The purpose of this step is to prepare for the removal of PPE. The doffing area should be separated into areas where early and later steps of doffing are conducted (e.g., separate chairs or ends of a bench). Before entering the PPE removal area, look for, clean, and disinfect (using an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html)) visible contamination on the PPE. As a final step before doffing, disinfect outer-gloved hands with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR,

and allow to dry. Verify that the trained observer is available in the PPE removal area before entering and beginning the removal process. Some facilities, especially those using PAPRs, might find it helpful to have a designated assistant to help with doffing. An assistant who is only assisting in doffing should wear the same PPE as the trained observer. If the doffing assistant is entering the patient's room (e.g. as a clinician), the assistant should wear the same PPE as other personnel entering the patient's room. The observer should not touch the person who is doffing and should not serve as the doffing assistant or "buddy." A mirror in the room can be useful for the healthcare worker while doffing PPE.

Section 9C. Doffing PPE, PAPR Option

Doffing PPE, PAPR Option – PPE should be doffed in the designated PPE removal area. Place all PPE waste in a leak-proof infectious waste container.

1. **Engage Trained Observer:** The doffing process should be supervised by the trained observer, who reads aloud each step of the procedure and confirms visually that the PPE is removed properly. Before the healthcare worker doffs PPE, the trained observer should coach and remind the healthcare worker to avoid reflexive actions that may put them at risk, such as touching their face. Post this instruction and repeat it verbally during doffing.
2. **Inspect:** Inspect the PPE to assess for visible contamination, cuts, or tears before starting to remove. If any PPE is visibly contaminated, then clean and disinfect using an EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html). If the facility conditions permit and appropriate regulations are followed, an *EPA-registered disinfectant spray (http://www.epa.gov/oppad001/list-l-ebola-virus.html) can be used, particularly on highly contaminated areas.
3. **Disinfect Outer Gloves:** Disinfect outer-gloved hands with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR, and allow to dry.
4. **Remove Apron (if used):** Remove (e.g., by breaking or untying neck strap and releasing waist ties) and roll the apron away from you, containing the soiled outer surface as you roll; discard apron taking care to avoid contaminating gloves or other surfaces.
5. **Inspect:** After removing the apron, inspect the PPE ensemble for visible contamination or cuts or tears. If visibly contaminated, then clean and disinfect affected areas using an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html).
6. **Disinfect and Remove Outer Gloves:** Disinfect outer-gloved hands with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR. Remove and discard outer gloves, taking care not to contaminate inner glove during removal process.

7. **Inspect and Disinfect Inner Gloves:** Inspect the inner gloves' outer surfaces for visible contamination, cuts, or tears. If an inner glove is visibly soiled, then disinfect the glove with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR, remove the inner gloves, perform hand hygiene with ABHR on bare hands, and don a new pair of gloves. If no visible contamination is identified on the inner gloves, then disinfect the inner-gloves with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR. If a cut or tear is detected on an inner glove, immediately review occupational exposure risk per hospital protocol.
8. **Remove Respirator with External Belt-Mounted Blower:** Remove the headpiece. The healthcare worker my need help removing the headpiece while still connected to the belt-mounted blower and filter unit. (Note: If a PAPR with a self-contained blower in the helmet is used, wait until step 14 to remove components.)
   a. Remove the belt-mounted blower unit and place all reusable PAPR components in an area or container designated for the collection of PAPR components for disinfection.
   b. Disinfect inner gloves with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR.
9. **Remove Gown *or* Coverall:** Remove and discard.
   a. Depending on gown design and location of fasteners, the healthcare worker can either untie fasteners, have the doffing assistant or "buddy" unfasten the gown, or gently break fasteners. Avoid contact of scrubs or disposable garments with outer surface of gown during removal. Pull gown away from body, rolling inside out and touching only the inside of the gown.
   b. To remove coverall, tilt head back and reach zipper or fasteners. Use a mirror to avoid contaminating skin or inner garments. Unzip or unfasten coverall completely before rolling down and turning inside out. Avoid contact of scrubs with outer surface of coverall during removal, touching only the inside of the coverall.
10. **Disinfect Inner Gloves:** Disinfect inner gloves with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR.
11. **Remove Boot Covers:** Sitting on a new clean surface (e.g., second clean chair, clean side of a bench) pull off boot covers, taking care not to contaminate pants legs.
12. **Disinfect Washable Shoes:** Use an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) to wipe down every external surface of the washable shoes.
13. **Disinfect Inner Gloves:** Disinfect inner gloves with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR.
14. **Remove Respirator (if not already removed):** If a PAPR with a self-contained blower in the helmet is used, remove all remaining components here.
   a. Remove and discard disposable hood.

b. Disinfect inner gloves with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR.
c. Remove helmet and the belt and battery unit. The healthcare worker may need help removing the PAPR.
d. Place all reusable PAPR components in an area or container designated to collect PAPR components for disinfection.

15. **Disinfect and Remove Inner Gloves:** Disinfect inner-gloved hands with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR. Remove and discard gloves, taking care not to contaminate bare hands during removal process.
16. **Perform Hand Hygiene:** Perform hand hygiene with ABHR.
17. **Inspect:** Both the trained observer and the healthcare worker perform a final inspection of the healthcare worker for contamination of surgical scrubs or disposable garments. If contamination is identified, the garments should be carefully removed and the wearer should shower immediately. The trained observer should immediately inform the infection preventionist or occupational safety and health coordinator or their designee for appropriate occupational health follow-up.
18. **Scrubs:** Healthcare worker can leave the PPE removal area wearing dedicated washable footwear and surgical scrubs or disposable garments, proceeding directly to showering area where these are removed.
19. **Protocol Evaluation/Medical Assessment:** Either the infection preventionist or occupational safety and health coordinator or their designee should meet with each healthcare worker on a regular basis to review the patient care activities performed, identify any concerns about care protocols and record the healthcare worker's level of fatigue.

Section 9D. Doffing PPE, N95 Respirator Option

Doffing PPE, N95 Respirator Option – PPE should be doffed in the designated PPE removal area. Place all PPE waste in a leak-proof infectious waste container.

1. **Engage Trained Observer:** The doffing process should be supervised by the trained observer, who reads aloud each step of the procedure and confirms visually that the PPE has been removed properly. Before doffing PPE, the trained observer must remind healthcare workers to avoid reflexive actions that may put them at risk, such as touching their face. Post this instruction and repeat it verbally during doffing.
2. **Inspect:** Inspect the PPE to assess for visible contamination, cuts, or tears before starting to remove. If any PPE is visibly contaminated, then disinfect using an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html). If the facility conditions permit and appropriate regulations are followed, an *EPA-registered disinfectant spray

(http://www.epa.gov/oppad001/list-l-ebola-virus.html) can be used, particularly on contaminated areas.

3. **Disinfect Outer Gloves:** Disinfect outer-gloved hands with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR.
4. **Remove Apron (if used):** Remove (e.g., by breaking or untying neck strap and releasing waist ties) and roll the apron away from you, containing the soiled outer surface as you roll; discard apron taking care to avoid contaminating gloves or other surfaces.
5. **Inspect:** After removing the apron, inspect the PPE ensemble for visible contamination or cuts or tears. If visibly contaminated, then clean and disinfect any affected areas by using an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html).
6. **Disinfect and Remove Outer Gloves:** Disinfect outer-gloved hands with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR. Remove and discard outer gloves, taking care not to contaminate inner gloves during removal process.
7. **Inspect and Disinfect Inner Gloves:** Inspect the inner gloves' outer surfaces for visible contamination, cuts, or tears. If an inner glove is visibly soiled, then disinfect the glove with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR, remove the inner gloves, perform hand hygiene with ABHR on bare hands, and don a new pair of gloves. If no visible contamination is identified on the inner gloves, then disinfect the inner-gloved hands with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR. If a cut or tear is detected on an inner glove, immediately review occupational exposure risk per hospital protocol.
8. **Remove Face Shield:** Remove the full face shield by tilting the head slightly forward, grasping the rear strap and pulling it gently over the head and allowing the face shield to fall forward, then discard. Care must be taken not to touch the face when removing the face shield. Avoid touching the front surface of the face shield.
9. **Disinfect Inner Gloves:** Disinfect inner gloves with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR.
10. **Remove Surgical Hood:** Unfasten (if applicable) surgical hood, gently remove, and discard. The doffing assistant or "buddy" can assist with unfastening hood.
11. **Disinfect Inner Gloves:** Disinfect inner gloves with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR.
12. **Remove Gown or Coverall:** Remove and discard.
    a. Depending on gown design and location of fasteners, the healthcare worker can untie fasteners, have the doffing assistant or "buddy" unfasten the gown, or gently break fasteners. Avoid contact of scrubs or disposable garments with outer surface of gown during removal. Pull gown away from body, rolling inside out and touching only the inside of the gown.

   b. To remove coverall, tilt head back to reach zipper or fasteners. Unzip or unfasten coverall completely before rolling down and turning inside out. Avoid contact of scrubs with outer surface of coverall during removal, touching only the inside of the coverall.
13. **Disinfect Inner Gloves:** Disinfect inner gloves with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR.
14. **Remove Boot Covers:** Sitting on a clean surface (e.g., second clean chair or clean side of a bench) pull off boot covers, taking care not to contaminate scrubs pants legs.
15. **Disinfect and Change Inner Gloves:** Disinfect inner gloves with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR.
    a. Remove and discard gloves taking care not to contaminate bare hands during removal process.
    b. Perform hand hygiene with ABHR.
    c. Don a new pair of inner gloves.
16. **Remove N95 Respirator:** Remove the N95 respirator by tilting the head slightly forward, grasping first the bottom tie or elastic strap, then the top tie or elastic strap, and remove without touching the front of the N95 respirator. Discard N95 respirator.
17. **Disinfect Inner Gloves:** Disinfect inner gloves with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR.
18. **Disinfect Washable Shoes:** Use an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) to wipe down every external surface of the washable shoes.
19. **Disinfect and Remove Inner Gloves:** Disinfect inner-gloved hands with either an *EPA-registered disinfectant wipe (http://www.epa.gov/oppad001/list-l-ebola-virus.html) or ABHR. Remove and discard gloves taking care not to contaminate bare hands during removal process.
20. **Perform Hand Hygiene:** Perform hand hygiene with ABHR.
21. **Inspect:** Both the trained observer and the healthcare worker perform a final inspection of healthcare worker for contamination of the surgical scrubs or disposable garments. If contamination is identified, the garments should be carefully removed and the wearer should shower immediately. The trained observer should immediately inform infection preventionist or occupational safety and health coordinator or their designee.
22. **Scrubs:** Healthcare worker can leave PPE removal area wearing dedicated washable footwear and surgical scrubs or disposable garments, proceeding directly to showering area where these are removed.
23. **Protocol Evaluation/Medical Assessment:** Either the infection preventionist or occupational health safety and health coordinator or their designee should meet with the healthcare worker on a regular basis to review the patient care activities performed, identify any concerns about care protocols, and record healthcare worker's level of fatigue.

Footnotes

*EPA-registered disinfectant wipe: Use a disposable wipe impregnated with a U.S. Environmental Protection Agency (EPA) -registered hospital disinfectant with a label claim for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus); see EPA list of Disinfectants for Use Against Ebola Virus at http://www.epa.gov/oppad001/list-i-ebola-virus.html (http://www.epa.gov/oppad001/list-i-ebola-virus.html).

Related Links

For U.S. Healthcare Settings: Donning and Doffing Personal Protective Equipment (PPE) for Evaluating Persons Under Investigation (PUIs) for Ebola Who Are Clinically Stable and Do Not Have Bleeding, Vomiting, or Diarrhea

Ebola PPE Frequently Asked Questions

File Formats Help:

How do I view different file formats (PDF, DOC, PPT, MPEG) on this site? (http://www.cdc.gov/Other/plugins/)

(http://www.cdc.gov/Other/plugins/#pdf)

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National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) (/ncezid/dw-index.html)
Division of Healthcare Quality Promotion (DHQP) (/ncezid/dhqp/index.html)

Appendix 5

Kansas
Department of Health and Environment

Kansas Health and Environmental Laboratories – Suspected Ebola Specimen Packaging and Shipping System Pictorial Guide

Note: Category A: An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. A list of Category A, Infectious Substances can be found in 49 CFR Parts 171-175 Hazardous Materials. Examples: Ebola Virus, Bacillus anthracis cultures, Brucella cultures, HIV cultures

Kansas
Department of Health and Environment

Kansas Health and Environmental Laboratories – Suspected Ebola Specimen Packaging and Shipping System Guide

1) Fiberboard and Styrofoam Infectious Shipping System with cold packs; Secondary Containers (95 kPa bags); Absorbent sleeves; Instruction Sheet; Shipper's Declaration.

2) Carefully read the Instruction Sheet provided in the Infectious Shipper.

3) Lavender (EDTA) Vacutainer with patient information.

NOTE: Do Not use Glass Tubes. Container must be secured with ParaFilm to prevent leaks.

4) Place primary container into absorbent sleeves. No more than 50mLs are allowed per shipping system.

5) Wrap and insert specimen into 95 kPa biohazard bag (secondary container). DO NOT put any paperwork inside secondary container.

6) Place bagged specimen on frozen cold pack inside Styrofoam Shipper.

7) Place second cold pack on top of specimen bag then replace Styrofoam container top.

8) Additional information can be placed on top of Styrofoam lid. Paperwork should be placed in a baggie and placed on the cooler lid.

9) Secure the flaps on the outer package of the system with tape and complete the mailing labels. 24-hr emergency telephone number is mandatory.

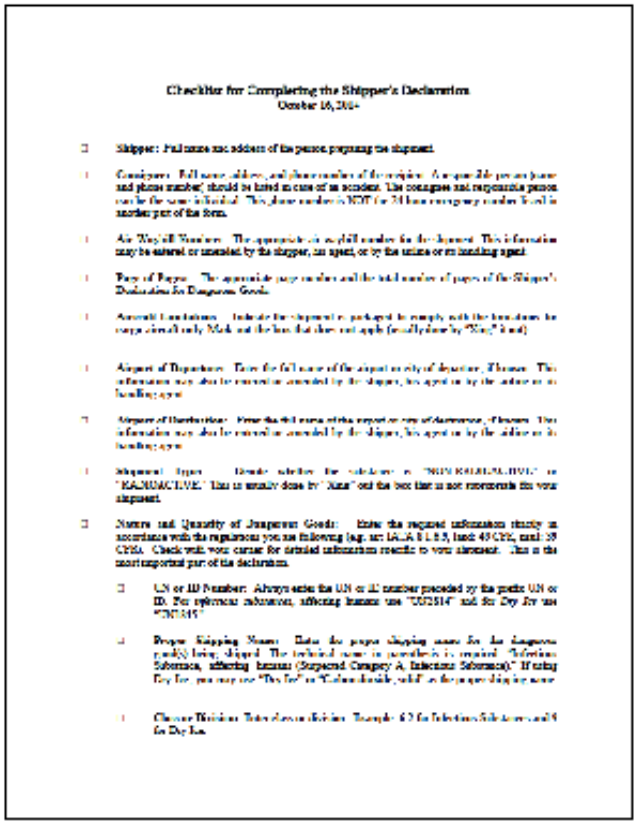
10) Proper Shipping Name is "Infectious Substance, Affecting Humans". In parentheses "Suspect Category A Infectious Substance".

11) Complete the Shipper's Declaration (see attached Checklist) and place in plastic pouch located on back of Infectious Shipper; seal the pouch.

12) Outer labeling includes: UN2814, orientation labels, class 6.2 infectious substance.

Kansas Health and Environmental Laboratories – Suspected Ebola Specimen Packaging and Shipping System Pictorial Guide

- Checklist



Checklist for Completing the Shipper's Declaration
October 16, 2014

☐ **Shipper:** Full name and address of the person preparing the shipment.

☐ **Consignee:** Full name, address, and phone number of the recipient. An organization's name and phone number should be listed in case of an accident. The consignee and responsible person can be the same individual. This phone number is NOT for 24 hour emergency number. It will be another part of the form.

☐ **Air Waybill Number:** The appropriate air waybill number for the shipment. This information may be entered or amended by the shipper, an agent, or by the airline or its handling agent.

☐ **Page of Pages:** The appropriate page number and the total number of pages of the Shipper's Declaration for Dangerous Goods.

☐ **Aircraft Limitations:** Indicate for shipment is packaged to comply with the limitations for cargo aircraft only. Mark out the box that does not apply (usually done by "Xing" it out).

☐ **Airport of Departure:** Enter the full name of the airport or city of departure, if known. This information may also be entered or amended by the shipper, his agent or by the airline or its handling agent.

☐ **Airport of Destination:** Enter the full name of the airport or city of destination, if known. This information may also be entered or amended by the shipper, his agent or by the airline or its handling agent.

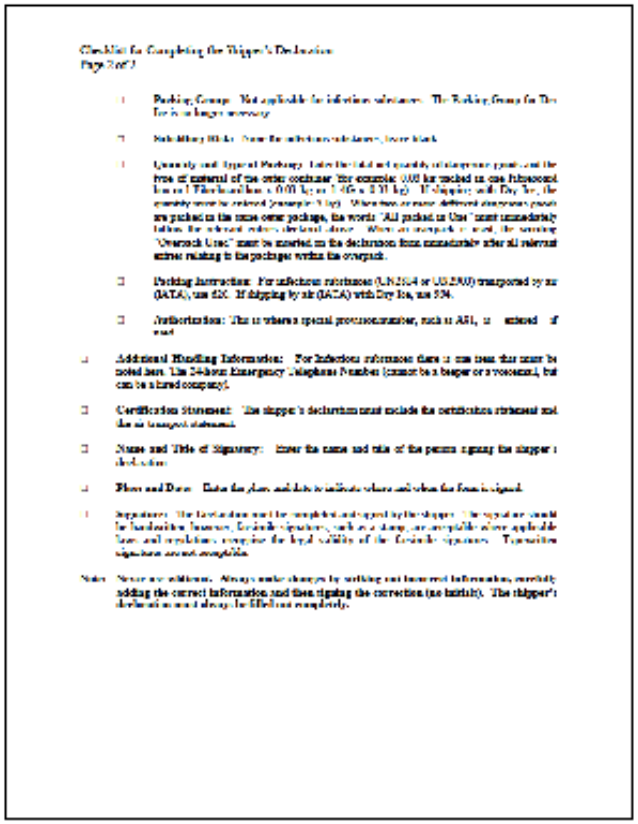
☐ **Shipment Type:** Beside subtitles for "NON RADIOACTIVE" or "RADIOACTIVE." This is usually done by "Xing" out the box that is not appropriate for your shipment.

☐ **Nature and Quantity of Dangerous Goods:** Enter the required information strictly in accordance with the regulations you are following (eg. see IATA 8.1.8.5, limit 45 CFR, limit 38 CFR). Check with your carrier for detailed information specific to your shipment. This is the most important part of the declaration.

☐ **UN or ID Number:** Always enter the UN or ID number preceded by the prefix UN or ID. For reference substance, affecting human use "UN3373" and for *Dry Ice* use "UN1845."

☐ **Proper Shipping Name:** Enter the proper shipping name for the dangerous good(s) being shipped. The technical name in parenthesis is required. "Infectious Substance, affecting humans (Suspected Category A Infectious Substance)." If using Dry Ice, you may use "Dry Ice" or "Carbon dioxide, solid" as the proper shipping name.

☐ **Class or Division:** Enter class or division. Example: 6.2 for Infectious Substances and 9 for Dry Ice.



Checklist for Completing the Shipper's Declaration
Page 2 of 2

☐ **Packing Group:** Not applicable for infectious substances. The Packing Group for Dry Ice is no longer necessary.

☐ **Subsidiary Risks:** Enter the subsidiary risk(s), if any, or leave blank.

☐ **Quantity and Type of Packing:** Enter the total net quantity of dangerous goods and the type of material of the outer container. For example: 0.05 kg packed in one fiberboard box or 1 Fiberboard box x 0.05 kg or 1 x 0.5 x 0.1 kg. If shipping with Dry Ice, the quantity must be entered (example: 5 kg). Where two or more different dangerous goods are packed in the same outer package, the words "All packed in One" must immediately follow the relevant entries for each dangerous good. Where an overpack is used, the wording "Overpack Used" must be inserted on the declaration form immediately after all relevant entries relating to the packages within the overpack.

☐ **Packing Instruction:** For infectious substances (UN 2814 or UN 2900) transported by air (IATA), use 620. If shipping by air (IATA) with Dry Ice, use 954.

☐ **Authorization:** This is where special provision number, such as A81, is entered if used.

☐ **Additional Handling Information:** For Infectious substances there is one item that must be noted here. The 24-hour Emergency Telephone Number (cannot be a beeper or a voicemail, but can be a hired company).

☐ **Certification Statement:** The shipper's declaration must include the certification statement and the no transport statement.

☐ **Name and Title of Signatory:** Enter the name and title of the person signing the shipper's declaration.

☐ **Place and Date:** Enter the place and date to indicate where and when the form is signed.

☐ **Signature:** The declaration must be completed and signed by the shipper. The signature should be handwritten; however, facsimile signatures, such as a stamp, are acceptable where applicable laws and regulations recognize the legal validity of the facsimile signature. Typewritten signatures are not acceptable.

Note: Never use whiteout. Always make changes by striking out incorrect information, carefully adding the correct information and then signing the correction (no initials). The shipper's declaration must always be filled out completely.

Checklist may also be found at the KDHE's website: http://www.kdheks.gov/labs/packaging_and_shipping.html

Appendix 6

Centers for Disease Control and Prevention

Guidance for U.S. Laboratories for Managing and Testing Routine Clinical Specimens When There is a Concern About Ebola Virus Disease

On this Page

Page Summary

Who this is for: Laboratory and other healthcare personnel handling and testing routine clinical specimens when concern about Ebola virus disease (EVD) has been raised by a physician.

What this is for: To provide updated guidance for management and evaluation of routine clinical specimens for differential testing and diagnoses other than EVD.

How to use: This guidance should be use as a supplement to CDC's *Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing in the United States*.

Print this page (javascript:window.print())

Purpose

Due to a heightened concern in the United States about Ebola, this document provides guidance for clinical laboratories on testing needed for the assessment and care of patients for which Ebola Virus Disease (EVD) is a concern, while minimizing risk to laboratory personnel.

Scope

This document updates and replaces the previously posted document: *How U.S. Laboratories Can Safely Manage Specimens from Persons Under Investigation for Ebola Virus Disease*.

Clinicians should maintain a high index of suspicion and consult their local and state health departments and CDC when ill travelers from Ebola-affected countries are identified; it is important to recognize that the likelihood of EVD even among symptomatic travelers returning from these countries is very low. In the hospital setting, where policies and procedures should be in place to safeguard health care workers, consideration of Ebola should not delay diagnostic assessments, laboratory testing, and appropriate care for other, more likely medical conditions[1]. This guidance is based on input received from numerous hospital and laboratory directors, infectious disease physicians, CDC Ebola response teams, and state health officials.

Key Points

1. CDC recommends that Ebola testing be conducted only for persons who meet the criteria for persons under investigation (PUIs) for EVD: A person who has both consistent signs or symptoms and risk factors as follows:
   - Elevated body temperature or subjective fever or symptoms, including severe headache, fatigue, muscle pain, vomiting, diarrhea, abdominal pain, or unexplained hemorrhage; **AND**
   - An epidemiological risk factor within the 21 days before the onset of symptoms.
2. If there is a clinical suspicion of Ebola, a determination whether a patient is, or is not a PUI should be made in consultation with public health officials as quickly as possible in order to ensure that patient care is not compromised. The period of time between when a clinical suspicion for Ebola is raised to the time a PUI determination is made can vary. Clinical laboratories, especially those in Ebola Assessment and Ebola Treatment Hospitals, should be prepared to provide a timely and minimum menu of testing to ensure that medical evaluation is not delayed for any patient; in the U.S., most of these persons will not have EVD, but have had another etiology for their illness[1]. Timely identification of these other etiologies is essential to appropriate patient care.
3. Presumptive testing for Ebola virus is available at 52 LRN laboratories (http://emergency.cdc.gov/lrn/) located throughout the United States. Hospitals should follow their state and/or local health department procedures for notifying and consulting about Ebola virus testing requests before contacting CDC.

4. Any presumptive positive Ebola test result must be confirmed at the CDC to inform public health decisions. For guidance on confirmatory Ebola virus testing, refer to *Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing in the United States*.
5. If a hospital chooses to use a commercial Ebola virus test, specimens should also be submitted to an LRN facility or CDC for definitive Ebola virus testing[2,3].
6. To minimize risk to personnel, a risk assessment must be performed by the laboratory director, safety officer, and other responsible persons to determine the potential for exposure from sprays, splashes, or aerosols generated during all laboratory processes, procedures, and activities. Risks should be mitigated by implementing engineering controls, administrative and work practice controls, and use of appropriate personal protective equipment (PPE).
7. To date, CDC considers the risk of acquiring EVD or other viral hemorrhagic diseases through laboratory testing to be low, but not zero risk. (See Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure). Some recommended measures to minimize the risk of laboratory transmission when testing patient specimens include: limiting the number of staff engaged in testing, evaluating and segregating equipment used for testing, and performing testing in a dedicated space.
8. The decision to perform testing in a hospital care laboratory using existing instrumentation, or alternatively, acquiring dedicated point of care (POC) instrumentation should be carefully evaluated. Considerations may include whether Ebola patient testing may lead to core laboratory instrumentation being removed from service, and the planning should include how to mitigate such potential outcomes.
9. The United States Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard (29 CFR 1910.1030) (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS) was developed to reduce the potential exposure of personnel to blood borne pathogens. All U.S. laboratories handling patient specimens are required to comply with this standard at all times; strict adherence is an initial step in providing protection to personnel.
10. U.S. hospitals or clinical laboratories concerned about a patient with potential Ebola virus exposure should contact their local and/or state health departments and CDC (770-488-7100).

Background

Ebola virus is transmitted through contact with infected blood or body fluids (e.g., urine, feces, and vomit) from symptomatic persons and with objects such as needles that have been contaminated with infected body fluids. PUIs for EVD should be managed by following appropriate precautions to prevent transmission of Ebola virus to others and contamination of the hospital environment. See CDC's infection control guidance.

In consultation with public health authorities, states are identifying hospitals which are capable of assessing persons that meet the criteria for persons under investigation (PUIs) for EVD. (see Interim Guidance for U.S. Hospital Preparedness for Patients with Possible or Confirmed Ebola Virus Disease: A Framework for a Tiered Approach and Interim Guidance for Preparing Ebola Assessment Hospitals). This document provides information that may be appropriate for all clinical laboratories. The guidance is especially important for Ebola Assessment Hospitals, which are designated facilities that are prepared to receive, isolate, and evaluate a PUI while the need for Ebola testing is assessed. If testing is warranted, these hospitals continue to provide patient care until an Ebola diagnosis can be confirmed or ruled out, and until a discharge or transfer is completed. Most PUIs will be identified through active monitoring of returned travelers, and directed to an Assessment Hospital. It is also possible that persons with unrecognized EVD will present to a Frontline healthcare facility (an acute care hospital or other emergency care setting including urgent care clinic, or critical access hospital) without prior notification; these facilities should be prepared to promptly identify and isolate these patients according to the CDC's guidance for emergency departments. Frontline healthcare facilities are not expected to provide prolonged care (>12–24 hours) for a severely ill patient. It is important to remember that due to the potential stigma associated with EVD, patients returning from affected countries may be reluctant to disclose their travel history.

Clinical Laboratory Testing of Clinical Specimens when Ebola Virus Disease is a Concern

CDC recommends that Ebola testing be conducted only for persons who meet the criteria for PUIs and have compatible clinical syndromes. If there is a clinical suspicion of Ebola, a PUI determination and medical evaluation should be made as quickly as possible in order to ensure patient care is not compromised. Most PUIs have had other etiologies for their illness such as malaria, influenza and other respiratory illnesses, typhoid fever, and other bacterial or viral infections[1]. Clinical laboratories should be prepared to provide sufficient testing to ensure patient care is not compromised while patients undergo assessment. The clinician should determine specific testing according to the patient presentation and travel history.

- U.S. hospitals or clinical laboratories concerned about a patient with potential Ebola virus exposure should contact their relevant local and state public health authorities. In joint consultation with CDC (770-488-7100), these agencies will assist in determining whether criteria for a PUI are met and appropriate measures for monitoring the patient will be determined in consultation with the attending health care provider.
- The decision to test for Ebola should not be made without consultation with public health officials. CDC should be notified immediately if a decision is made to test. CDC considers a single diagnostic test used in the absence of a confirmatory diagnostic algorithm insufficient for public

health decision-making. If a hospital chooses to use a commercial Ebola virus test, specimens should also be submitted concurrently to an LRN facility or CDC for definitive Ebola virus testing[2,3].

CDC and state health department laboratories are available to assist hospitals in the selection, interpretation, and sourcing of additional laboratory tests needed to manage PUIs.

Although laboratory testing for patients for which there is a clinical suspicion of EVD, or a patient with confirmed EVD will likely vary, assessment and treatment facilities should consider how they might safely perform the following laboratory tests (if indicated) or, if unable to safely perform specific tests, identify alternative approaches to patient management (e.g. empiric treatments, alternative diagnostic strategies):

- A complete blood count (CBC), including differential, and platelet count
- Sodium, potassium, chloride, bicarbonate, calcium, blood urea nitrogen, creatinine, and glucose concentrations
- Aspartate aminotransferase (AST), alanine aminotransferase (ALT), and total bilirubin
- Coagulation testing, specifically prothrombin time (PT), expressed as international normalized ratio (INR)
- Blood culture for bacterial pathogens (for information on automated or manual blood cultures, see "Laboratory Equipment" section of this document).
- Malaria testing (smear or rapid tests)

Note: While not all facilities may have the capacity to definitively diagnose malaria, any facility capable of performing a complete blood count should be able to review the blood smear to provide an initial presumptive diagnosis regarding the presence or absence of malaria parasites. Facilities that do not have the capacity to perform definitive malaria testing on site should contact their state health department to facilitate the definitive diagnosis; CDC and the state health departments can assist with providing a diagnosis of malaria in a timely fashion. More information can be found at CDC's malaria website (http://www.cdc.gov/malaria/new_info/2014/malaria_ebola.htm).

- Influenza virus testing*
- Respiratory Syncytial Virus (RSV) and other respiratory virus testing*+
- Rapid group A strep testing on throat swabs
- Urinalysis

Ebola treatment hospitals should be able to provide the above tests, as well as additional testing required to manage a patient with EVD.

* Negative results when using point of care rapid diagnostics on respiratory specimens from older children and adults do not exclude infection because of their lower sensitivity compared with molecular assays. However, rapid RSV antigen testing in smaller children has been shown to be effective.

+ Molecular assays for numerous respiratory viruses are often available as multiplex assays and may aid in diagnosis of common respiratory infections

Compliance with Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard

All laboratory personnel who collect, handle, or test human specimens must comply with the United States Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard (29 CFR § 1910.1030) (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS)[4]. Performance of site-specific risk assessments should consider the path of the sample throughout the laboratory, including all work processes, procedures and tasks to identify potential exposure risks and to mitigate these risks by implementing engineering controls, administrative controls (including work practices), and appropriate PPE. This is a well-recognized standard that was developed to protect laboratory personnel from exposure. U.S. hospitals have safely managed patients with viral hemorrhagic fevers (VHF), even when the diagnosis of VHF was only made after patient discharge[5,6,7,8,9].

Risk Assessment and Mitigation

Laboratory risk assessment is a process used to identify: 1) the hazards associated with a known or potentially infectious agent and the activities being conducted with them; 2) the likelihood of a person's exposure to that agent or material; and 3) the consequences of such an exposure to personnel or equipment (e.g., a laboratory acquired infection or the need to take a machine off-line for extended periods)[10].

A risk assessment of all processes, procedures, and activities in the laboratory must be performed to determine the potential for exposure to the specimen through generation of aerosols, sprays, splashes, or spills. Based on the assessment, a plan to mitigate the identified risks should be implemented using engineering controls, administrative controls (including work practices), and use of appropriate PPE (see section below).

CDC is aware of hospitals that have safely used instruments in their core laboratories to test specimens when EVD is a concern, however, following risk assessment, laboratories may choose to use point of care testing or other alternative procedures to minimize disruption to the core laboratory and minimize risk to laboratory personnel.

Some items for clinical laboratories to focus on during their site-specific risk assessment should include:

- Specimen management and transport, including the path of the sample through the laboratory particularly avoiding transport through high-traffic areas or pneumatic tube systems
- Equipment hazards (e.g., the potential for creating aerosols, sprays, splashes of the specimen when performing testing and using equipment)
- Biological Safety Cabinet certification, operation and safe work practices
- Decontamination procedures, including spill response, and methods for decontamination of equipment
- Infectious waste management
- Laboratory design
  - Laboratories that have open room designs should also consider the risk of exposure to workers present in the area but that are not directly involved with testing of a particular sample
  - Some recommended measures to minimize the risk of laboratory transmission when testing patient specimens include: limiting the number of staff engaged in testing, evaluating and segregating equipment used for testing, and performing testing in a dedicated space
- Engineering controls and safety equipment
- Laboratory communication protocols
- Laboratory entry and exit procedures
- PPE selection and use
- Facility ventilation and filtration
- Employee medical surveillance and exposure response
- Safe sharps handling
- Personnel safety training and competencies

Additional information on conducting a risk assessment can be found in the CLSI Document M29-A4 "*Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition*"[11].

PPE

Laboratory workers may use a variety of PPE to prevent transmission of infectious pathogens to staff during the collection, processing, and testing of patient specimens.

Appropriate PPE should be based on a risk assessment of the situation, the work being done, as well as the capabilities of the user. Too much PPE can be just as hazardous as too little, resulting in limited visibility, mobility and potential heat stress issues; ill-fitting PPE can cause distraction and reduced sensory perception.

- PPE must be provided to the employees free of cost by the employer as required by the OSHA bloodborne pathogens standard
- PPE must prevent blood or other potentially infectious materials from passing through and reaching the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes
- Each laboratory should work with its institution's infection control and laboratory safety departments to ensure laboratory personnel safety
- PPE selected must not be compromised by chemicals used in laboratory procedures
- Consideration may be given to using a buddy system to ensure that safe donning and doffing procedures are followed
- Consultation with CDC is available to assist laboratories with selecting appropriate PPE (770-488-7100)

Laboratory staff **must** be trained in the proper donning and doffing of PPE. The proper donning and doffing of PPE is critical for worker safety, and strict adherence to protocols is essential.

1. PPE to be used during specimen collection

Healthcare personnel including laboratory staff that collect patient specimens from a confirmed patient or a PUI exhibiting obvious bleeding, vomiting or diarrhea or who is clinically unstable and/or will require invasive or aerosol-generating procedures should wear the PPE described in the hospital guidance.

Healthcare personnel caring for a PUI who is clinically stable and does not have bleeding, vomiting or diarrhea can wear the alternate ensemble described in the ED guidance and on the Assessment hospital page.

2. PPE to be used when performing laboratory testing

It is strongly recommended to work inside a certified Class I or certified Class II biosafety cabinet (BSC) when handling or manipulating patient specimens. When all proper procedures are strictly followed, a Class I BSC will protect the worker, and a Class II BSC will protect the worker and the sample from contamination.

When manipulating clinical specimens when EVD is a concern, staff should use a combination of engineering controls, work practices and PPE to protect their mouth, nose, eyes and bare skin from coming into contact with patient specimens, including:

- Proper use of a certified Class I or Class II biosafety cabinet AND
  - Disposable gloves
  - Solid-front wrap around gowns that are fluid-resistant or fluid-impermeable
  - Surgical mask to cover all of nose and mouth
  - Eye protection such as a full face shield or goggles/safety glasses with side shields
- Manufacturer-installed safety features for instruments that reduce the likelihood of exposure

Clinical laboratories may decide to include additional PPE that may necessitate additional requirements, (i.e., staff must be fit tested and medically cleared to wear an N-95 respirator). The facility must provide additional training and have staff practice these procedures using the PPE before using them in the workplace. Using unfamiliar equipment or PPE without sufficient training and practice may lead to inadvertent breaches in safe practices and may increase a person's risk of contaminating his or her clothes, mouth, or eyes, especially when removing PPE. Consistency of these planned procedures is essential to protect personnel.

Laboratory Equipment

Some laboratory equipment used for routine testing may not be appropriate for testing specimens from PUIs because: (a) The equipment may generate an aerosol or (b) recommended disinfectants to inactivate Ebola virus may affect the performance of the instrument or void the manufacturer's warranty. CDC and FDA are currently working with manufacturers to assess and resolve the safety issues of laboratory equipment for testing specimens from PUIs.

Some considerations regarding use of laboratory equipment are:

- Laboratories should consider using equipment with closed tube systems in which the specimen container (e.g., vacutainer tube) stays capped during testing.
- Centrifugation can pose a risk of aerosolization. If centrifugation is necessary for testing, centrifuges should have sealed buckets or sealed rotors. After centrifugation, the sealed buckets or rotors should be opened inside a biosafety cabinet.
- Automated blood culture instruments have been used in the core lab after careful evaluation of the risk assessment, ensuring that the outside of the bottle is cleaned with a disinfectant labeled for non-enveloped viruses before putting it in the instrument, and ensuring that staff who handle the bottles are wearing gloves. Alternatively, benchtop blood culture instruments are available, or blood culture bottles may be incubated manually in separate incubators and monitored for turbidity as an indication of growth. Subculture of any positive blood culture

bottles should be performed within a biosafety cabinet in a separate laboratory area segregated from the core lab, preferably by using commercially available "venting unit" devices that sheath the needle during extraction of blood from the bottle to prevent needlesticks.

Point of Care (POC) Testing

If POC instruments are used, the clinical laboratory director must ensure they meet their intended use, as approved by the Food and Drug Administration (FDA). This information is specified in the "Intended Use" section of the Product Insert.

1. If the intended use of the instrument **excludes testing of critically ill patients**:
   a. Then use of the POC instrument for testing critically ill patients is considered off-label use. Before reporting patient results, the laboratory must establish the performance specifications for accuracy, precision, sensitivity, specificity, reportable range of test results, reference intervals and any other performance characteristic required for test performance in a critically ill patient population. Validation must be performed **prior to use** for testing patient specimens.
   b. In addition to establishing performance specifications for the specific use of the test, the laboratory must also comply with the relevant provisions of the CLIA regulations (http://wwwn.cdc.gov/clia/Regulatory/default.aspx) (42 CFR Part 493) and document performance of quality control and proficiency testing, and that relevant laboratory education/experience qualifications are met by laboratory directors and testing personnel.
2. It is recommended to place point of care (POC) instruments within an enclosure or behind a barrier to contain any splashes or potential aerosols that may be generated.
   a. If placed inside a BSC, ensure that appropriate airflow is not compromised by overloading the inside of the BSC, or by blocking the front or back air intake grilles. Consideration should be given to verifying inward airflow at the front opening of the BSC while instruments are operating.
   b. When a BSC is not available or possible, then additional safety equipment should be used to contain any splashes or potential aerosols generated. This could be a small benchtop BSC, a PCR workstation (e.g., "dead air box"), a plexiglass splash shield, or other physical containment device.
3. If clinical laboratories decide to add POC instruments specifically for testing specimens from PUIs, staff should be trained and should practice these procedures in advance while wearing the appropriate PPE.

NOTE: See Appendix 1 for questions to consider when selecting instruments and for a list of instruments identified by institutions that have cared for patients with EVD. This list does not indicate an endorsement of the product nor should this be considered a complete list of all test instruments that may be acceptable.

Transporting Patient Specimens within the Facility

- Primary specimen containers should only be handled with proper PPE, including gloves.
- Before removing patient specimens from the site of care, it is advisable to plan the route of the sample from the bedside to the laboratory or testing area in order to avoid high-traffic areas.
- Before removing patient specimens from the site of care, the outside of the specimen containers should be decontaminated with an approved disinfectant as described in Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus.

Note: Recommended disinfectants are those known to kill non-enveloped viruses and can be found in List L of Disinfectants for Use Against the Ebola Virus (http://www.epa.gov/oppad001/list-l-ebola-virus.html). This list of registered disinfectants meets the CDC's criteria for use against the Ebola virus on hard, non-porous surfaces.

- In compliance with 29 CFR §1910.1030, specimens should be placed in a durable, leak-proof secondary container.
- After placement in a secondary container, specimens should be hand-carried to the laboratory. DO NOT use any pneumatic tube system (automated or vacuum specimen delivery system) for transporting specimens.

Transporting Specimens from PUIs to Sites Outside of the Facility

Ebola virus is classified as a Category A infectious substance by the Department of Transportation (DOT). Specimens from PUIs or patients confirmed to have Ebola virus infection should be packaged and shipped as Category A infectious substances. For guidance on packaging and shipping, refer to *Guidance for Collection, Transport and Submission of Samples for Ebola Virus Testing in the United States* and the DOT Hazardous Materials Regulations (HMR) (http://www.ecfr.gov/cgi-bin/text-idx?SID=dde5869266c7e8f4c8b22f63ee53c2db&tpl=/ecfrbrowse/Title49/49CIsubchapC.tpl).

Decontamination

As noted above, recommended disinfectants are those known to kill non-enveloped viruses and can be found in List L of Disinfectants for Use Against the Ebola Virus (http://www.epa.gov/oppad001/list-l-ebola-virus.html). These disinfectants should be used for cleaning and disinfecting of testing surfaces, handling spills, and cleaning and decontamination of laboratory equipment.

1. Cleaning and Disinfecting of Testing Surfaces

See the Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus for recommendations regarding the cleaning and disinfection of patient care area surfaces including the management of blood and body fluid spills. These recommendations also apply to cleaning and disinfecting in a laboratory where specimens are being processed from PUIs or patients with confirmed EVD.

2. Handling Spills

The basic principles for blood or body substance spill management are outlined in the OSHA Bloodborne Pathogens Standard[2]. CDC guidelines recommend removal of bulk spill material, cleaning the site, and then disinfecting the site with a disinfectant effective against the potential agent. Points to consider are:

- Limit the number of personnel involved in the clean-up
- Develop protocols for safely remediating spills containing broken glass
- Before any spill clean-up is initiated, ensure staff are trained and wear recommended PPE to protect against direct skin and mucous membrane exposure of cleaning chemicals, contamination, and splashes, including, at a minimum:
  - Disposable gloves
  - Solid-front wrap- around gowns that are fluid-resistant or fluid-impermeable
  - N-95 rated respirator (staff must be fit tested and medically cleared), or surgical mask to cover all of nose and mouth
  - Eye protection such as a full face shield or goggles/safety glasses with side shields
- All materials used for cleanup must be treated as infectious and disposed of in a biohazard waste container

3. Decontamination of Equipment

- For decontamination of laboratory instruments and equipment, use of an EPA-registered hospital disinfectant with label claims for non-enveloped viruses (e.g., norovirus, rotavirus, adenovirus, and poliovirus) for cleaning and decontaminating surfaces or objects is recommended.
- The laboratory should consult in advance with the manufacturer to ensure the most appropriate selection of such disinfectants and their use on the equipment. Some disinfectants can be detrimental (i.e., corrosive) to the instrument's surface.
- The Operator's Manual should be consulted to see what the manufacturer recommends when taking the equipment out of commission or preparing for maintenance or repairs. CDC is aware of the challenges laboratory workers and their institutions face when these instructions are not

provided in the manuals and is in consultation with FDA and the manufacturers to resolve these issues.

If an instrument is contaminated during use and there is no procedure for decontamination of the internal compartments without compromising the instrument operability, then the instrument may need to be removed from service as there are no other validated methods for ensuring that any remaining viral particles are no longer viable.

Laboratory Waste Management

- Ebola virus is classified as a Category A infectious substance by the Department of Transportation (DOT) and, when transported in commerce, is regulated by DOT's Hazardous Materials Regulations (HMR, 49 C.F.R., Parts 171-180). Any item transported in commerce that is contaminated or suspected of being contaminated with a Category A infectious substance must be packaged and transported in accordance with the HMR. This includes untreated patient specimens from PUIs, medical equipment, sharps, linens, and used health care products (such as soiled absorbent pads or dressings, kidney-shaped emesis pans, portable toilets, used PPE (e.g. gowns, masks, gloves, goggles, face shields, respirators, booties, etc.), or byproducts of cleaning.
- For solid waste generated during laboratory testing, OSHA Bloodborne Pathogen Standard (29 CFR § 1910.1030) specifies that:
  1. Potentially infectious materials shall be placed in a primary container which prevents leakage during collection, handling, processing, storage, transport, or shipping
  2. The primary container shall be placed within a second container which is puncture-resistant and prevents leakage during handling, processing, storage, transport, or shipping
- If available and proper procedures are strictly adhered to, steam sterilization (autoclaving) as a waste treatment process will inactivate the virus. If used, there are numerous requirements that must be followed for the safe and effective operation of autoclaves. After waste from PUIs or confirmed for EVD has been autoclaved, it can be combined with the laboratory waste stream as regulated (non-class A) medical waste.
- If an autoclave is not available in the facility, other arrangements must be made with a licensed external waste contractor to transport, treat, and dispose of the waste. Permits are required and other restrictions may apply based on state or local regulations.
- The regulations associated with disposal of biohazards are complex, and vary by state and local requirements. Check with your state's medical waste management program for more guidance on solid and liquid waste.
- Waste generated during the handling and testing of specimens from PUIs or patients with confirmed EVD is not subject to Federal Select Agent regulations (42 CFR § 73.3(d)(1)), **UNLESS viable** Ebola virus is **intentionally** isolated from that waste.

Considerations of Select Agent Concerns

As outlined in the Interim Guidance Regarding Compliance with Select Agent Regulations for Laboratories Handling Patient Specimens that are Known or Suspected to Contain Ebola Virus[13], specimens from PUIs are not select agents. Patient specimens that have been proven to contain infectious Ebola virus by viral isolation may be classified as select agents. CDC will work with the facility to determine proper reporting and handling of specimens from these patients.

Appendix 1: Laboratory Equipment

A. Selecting Laboratory Equipment

Clinical laboratories need to be prepared to test clinical specimens to support patient care when EVD is a concern. Below are suggested questions to facilitate decision making regarding selecting or using laboratory instruments to test these specimens.

1. Is the specimen contained within a closed chamber and does it remain contained within a closed chamber throughout testing?
2. Even if the specimen remains contained within a closed chamber, has an evaluation been performed to determine if the manufacturer's safety features are effective in protecting instrument operators from exposure to aerosols or sprays from patient specimens?
3. If the specimen container is opened during testing, have the potential routes of exposure to the operator during sample preparation and testing been identified, and have engineering controls and/or PPE been implemented?
4. Does the instrument employ wash and decontamination solutions in its test system to adequately inactivate bloodborne pathogens, including Ebola virus?
5. Does the manufacturer provide hazard warnings and PPE guidance with their troubleshooting instructions?
6. Have the potential exposure routes associated with handling and transport of the instrument's on-board waste collection been identified and PPE evaluated and implemented?
7. How close is the instrument to other operations in the laboratory?
8. Are there instructions for cleaning and decontaminating the instrument, including track systems?
9. Do recommended disinfectants meet the EPA requirements for inactivating non-enveloped viruses?

For POC instruments under consideration for use in isolation areas, refer to questions 1-8 above in addition to the following:

1. What are the size and operational requirements of the entire test system? Consider the instrument's environmental operating requirements including temperature and humidity, and proper reagent storage (e.g., refrigerator or freezer).
2. Does the "Intended Use" statement of the device labeling allow for testing critically ill patients? (FDA has not approved the use of some devices for testing critically ill patients.)
3. If the instrument is placed inside a BSC, will it compromise the proper BSC operation and protective functions (e.g., air flow)?
4. Is the instrument difficult to operate while wearing required PPE?
5. Is the instrument easily decontaminated?

Laboratory equipment used by some laboratories testing Ebola virus-positive specimens

Some U.S. hospitals have treated patients who tested positive for Ebola virus. The following table lists instruments these hospitals selected to conduct clinical laboratory testing on these patients. The conditions under which hospital laboratories used these instruments varied; some chose to place these instruments in a biosafety cabinet, whereas others operated them under BSL 2 or BSL 3 conditions[14,15].

Note: POC testing instruments placed inside a biosafety cabinet (BSC) may interfere with the BSC airflow and compromise staff safety. Care should be taken not to overload the BSC with equipment, and consideration should be given to verifying inward airflow at the front opening of the BSC while instruments inside are operating.

The following is a list generated from **institutions other than CDC**. This list is for information only and **is not intended as a CDC endorsement of these instruments or practices**, nor should this be considered a complete list of all test instruments that may be acceptable.

Clinical Chemistry

Manufacturer	Device
Beckman Coulter	DxC880i
Abbott Laboratories	ISTAT
Abaxis	Piccolo Xpress

Coagulation

Manufacturer	Device

Manufacturer	Device
ITC	Hemochron Signature Elite
F. Hoffman-La Roche	CoaguChek

Hematology

Manufacturer	Device
Sysmex	XN 9000 pocH 100i

Microbiology

Test	Method
Blood Culture	Plastic bottles/manual monitoring method
Malaria	Smear fixed in methanol for 15 mins Alere BinaxNOW
Ebola virus testing	Biofire FilmArray*

*If used, this test result is presumptive only and must be confirmed at CDC.

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File Formats Help:

How do I view different file formats (PDF, DOC, PPT, MPEG) on this site? (http://www.cdc.gov/Other/plugins/)

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National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) (/ncezid/dw-index.html)

Division of Healthcare Quality Promotion (DHQP) (/ncezid/dhqp/index.html)

Centers for Disease Control and Prevention

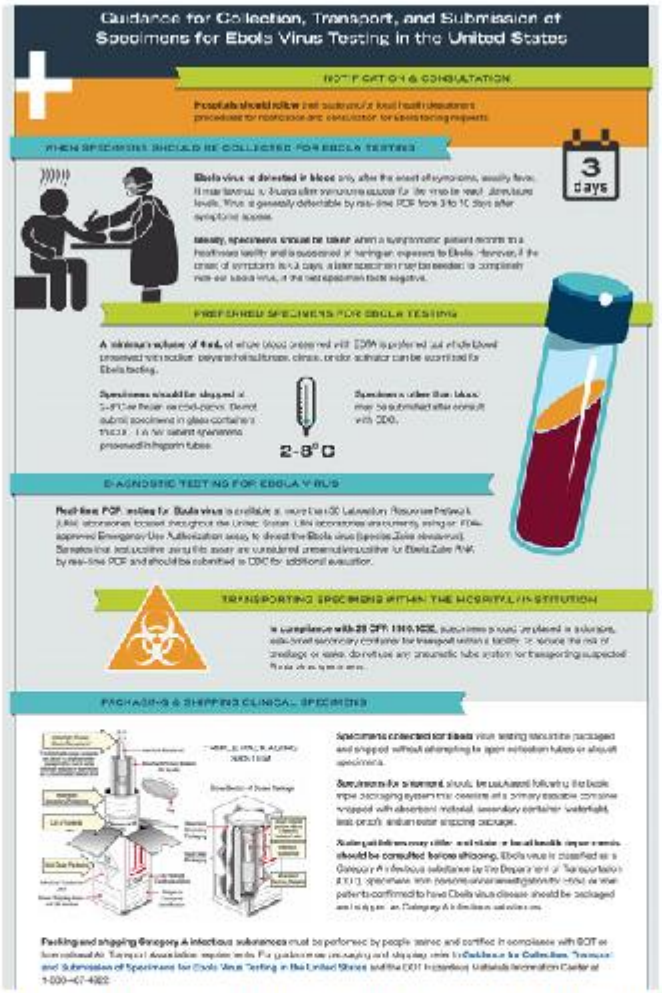
Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing

Updated: January 30, 2015

Print this page (javascript:window.print())

Purpose

Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing... Page 2 of 9



Guidance for Collection, Transport, and Submission of Specimens for Ebola Virus Testing in the United States [PDF - 1 page]

To provide guidance for laboratory workers on collecting, transporting and submitting specimens for Ebola virus testing.

Scope

http://www.cdc.gov/vhf/ebola/healthcare-us/laboratories/specimens.html 9/25/2015

This guidance document replaces the previously posted document: "*Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Persons Under Investigation (PUIs) for Ebola Virus Disease (EVD) in the United States.*"

This document complements the updated CDC "*Guidance for U.S. Laboratories for Managing and Testing Routine Clinical Specimens When There is a Concern About Ebola Virus Disease*" which provides guidance for clinical laboratories on testing needed for assessment and care of patients for whom Ebola Virus Disease (EVD) may be a concern, while minimizing risk to laboratory personnel.

This guidance is based on input received from numerous hospital and laboratory directors, infectious disease physicians, CDC Ebola response teams, and state health officials.

Key Points

1. CDC recommends that Ebola testing be conducted only for persons who meet the criteria for persons under investigation (PUIs) for EVD. A PUI is a person who has both consistent signs and/or symptoms, including:
   - Elevated body temperature or subjective fever or symptoms, including severe headache, fatigue, muscle pain, vomiting, diarrhea, abdominal pain, or unexplained hemorrhage, AND
   - An epidemiological risk factor within the 21 days preceding the onset of symptoms.
2. U.S. hospitals or clinical laboratories concerned about a patient with potential Ebola virus exposure should contact their local and/or state public health authorities. These agencies will work with CDC to determine whether a patient is or is not a PUI, and whether testing is indicated. Patient status should be determined as quickly as possible in order to ensure that patient care is not compromised.
3. Presumptive testing for Ebola virus is available at over 50 LRN laboratories (http://emergency.cdc.gov/lrn/) located throughout the United States. Any presumptive positive Ebola test result must be confirmed at the CDC to inform public health decisions.
4. If it is determined that testing for Ebola virus is indicated, at least 4 mL of whole blood collected in a plastic tube preserved with EDTA is the preferred sample for testing. Specimens should be shipped with refrigerant to maintain 2°–8°C to the designated LRN laboratory.
5. If the PUI symptoms have been present for < 3 days, a second sample collected 72 hours after onset of symptoms may be required to definitively rule out Ebola.
6. To minimize risk to personnel, a site-specific risk assessment must be performed by the laboratory director, safety officer, and other responsible persons prior to receiving specimens in order to determine the potential for exposure from sprays, splashes, or aerosols generated during all laboratory processes, procedures, and activities. Risks should be mitigated by implementing engineering controls, administrative and work practice controls, and use of appropriate personal protective equipment (PPE).

7. Ebola virus is classified as a Category A infectious substance by the Department of Transportation (DOT) and transport of samples from PUIs or patients confirmed or suspected of having EVD is regulated by DOT's Hazardous Materials Regulations (HMR) 49 CFR 171-180 (http://www.ecfr.gov/cgi-bin/text-idx?SID=2a97f2935677211e1785ac643163d2a9&node=49:2.1.1.3.10.5.25.33&rgn=div8). Specimens for shipment should be packaged following the basic triple packaging system consisting of (1) a primary container (a sealable specimen container) wrapped with absorbent material, (2) a secondary container (watertight, leak-proof), and (3) an outer shipping package.
8. The United States Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard (29 CFR 1910.1030) (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS) was developed to reduce the potential exposure of personnel to bloodborne pathogens. All U.S. laboratories handling patient specimens are required to comply with this standard at all times; strict adherence is an initial step in providing protection to personnel.

Background

Ebola virus can cause a severe, often fatal disease in humans and nonhuman primates. It is transmitted through contact with infected blood or body fluids (e.g., urine, stool, and vomit) and with objects such as needles that have been contaminated with infected body fluids. The incubation period is usually 8–10 days (ranging from 2 to 21 days). Patients can transmit Ebola virus once symptoms appear and through the later stages of disease, as well as postmortem. PUIs should be managed by following appropriate precautions to prevent transmission of Ebola virus to others and the hospital environment; for guidance on infection control, see CDC infection control guidance.

Diagnosing Ebola in a person who has been infected for only a few days may be complicated. The early symptoms of Ebola infection are difficult to distinguish from other, more common infectious diseases such as such as malaria, influenza, and typhoid fever. Ebola virus is detected in blood only after onset of symptoms, most notably fever, which accompany the rise in circulating virus; however, it may take up to 3 days after symptoms begin for the virus to reach detectable levels.

CDC recommends that Ebola testing be conducted only for persons who meet the criteria for persons under investigation (PUIs) for Ebola virus disease. Presumptive Ebola testing is available at over 50 LRN laboratories and confirmatory Ebola testing is available at the CDC. U.S. hospitals or clinical laboratories concerned about a patient with potential Ebola virus exposure should contact their local and state public health authorities before contacting CDC. In joint consultation with CDC (770-488-7100), these agencies will assist in determining whether testing is indicated. **No specimens will be accepted by CDC laboratories without prior consultation with CDC.**

Collecting Specimens for Ebola Testing

- Specimens should be obtained when a patient meets the criteria for person under investigation (PUI) including patients with clinical signs, symptoms, **and** epidemiologic risk factors for Ebola virus disease. If the first specimen is obtained 1-3 days after the onset of symptoms and tests negative and the patient remains symptomatic without another diagnosis, a later specimen may be needed to rule-out Ebola virus infection.
- Staff who collect specimens from PUIs should wear appropriate PPE and should refer to Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing).
- For adults, a minimum volume of 4 mL whole blood is preferable. For pediatric samples, a minimum of 1 mL whole blood should be collected in pediatric-sized collection tubes. Blood must be collected in **plastic** collection tubes. Do not transport or ship specimens in glass containers or in heparinized tubes.
- Whole blood preserved with EDTA is preferred, but whole blood preserved with sodium polyanethol sulfonate, citrate or with clot activator is also acceptable.
- Do not separate and remove serum or plasma from the primary collection container.
- Specimens should be packaged and transported at 2°–8°C with cold-packs to the final testing destination.
- Specimens other than blood may be submitted after consultation with CDC by calling the EOC at 770-488-7100.

Storing Clinical Specimens for Ebola Testing

If necessary, short-term storage of specimens before shipping should be at 4°C or frozen.

Diagnostic Testing for Ebola Virus

Real-time PCR testing for Ebola virus is available at over 50 LRN laboratories located throughout the United States. LRN laboratories are currently using an FDA approved Emergency Use Only (EUA) assay to detect the Ebola (Zaire species) virus. Samples that test positive using this assay are considered presumptive positive for Ebola Zaire RNA by real time RT-PCR and should be submitted to CDC for additional evaluation.

Transporting Specimens within the Facility

- PPE to be worn during transport within the facility should be determined by a site-specific risk assessment, and may vary among facilities. Recommendations for PPE include disposable fluid-resistant closed lab coat, disposable gloves, covered legs and closed-toed shoes.

- Before removing patient specimens from the site of care, it is advisable to plan the route of the sample from the patient area to the location where it will be packed for shipping in order to avoid high traffic areas.
- Before removing patient specimens from the site of care, the outside of the specimen containers should be decontaminated with an approved disinfectant as described in Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus.

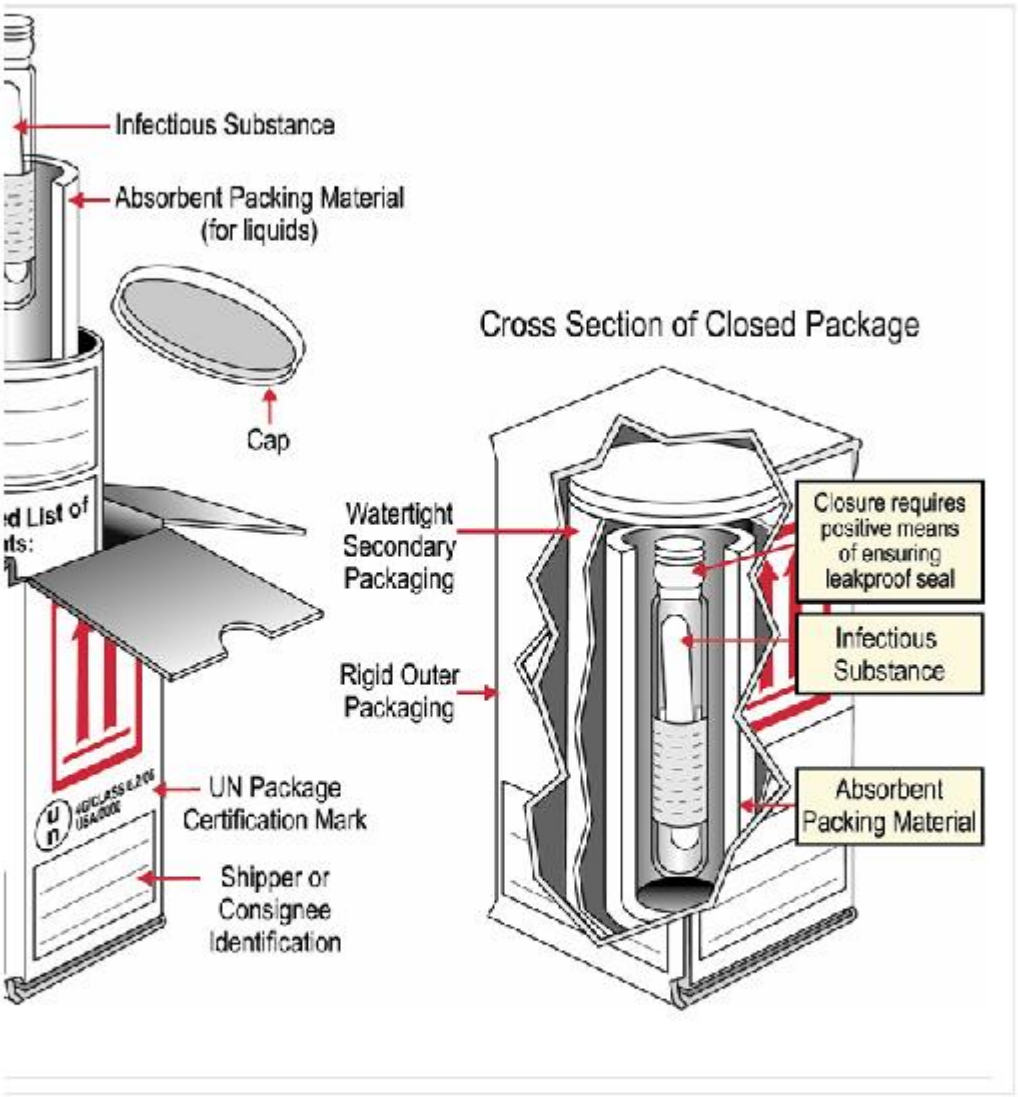
Note: Recommended disinfectants are those known to kill non-enveloped viruses and can be found in List L of EPA's Disinfectants for Use Against the Ebola Virus (http://www.epa.gov/oppad001/list-l-ebola-virus.html). This list of registered disinfectants meets the CDC's criteria for use against the Ebola virus on hard, non-porous surfaces.

- In compliance with OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030 (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS)), specimens should be placed in a durable, leak-proof secondary container.
- After placing in a secondary container, specimens should be hand-carried to the laboratory or packing area. DO NOT use any pneumatic tube system (automated or vacuum specimen delivery system) for transporting specimens.

Transporting Specimens for Ebola Testing to Sites Outside the Facility

- Samples from patients that are suspected of or confirmed to have Ebola virus infection should be packaged and shipped as Category A infectious substances in accordance with the DOT's Hazardous Materials Regulations (HMR) 49 CFR 171-180 (http://www.ecfr.gov/cgi-bin/text-idx?SID=6094f4c86cef1403550ec3f80babfb85&tpl=/ecfrbrowse/Title49/49CIsubchapC.tpl).
- All persons packing and shipping infectious substances must be trained and certified in compliance with DOT or the International Air Transport Association (http://www.iata.org/Pages/default.aspx) (IATA) requirements every two years.
- Specimens collected for Ebola virus testing should be packed and shipped without attempting to open collection tubes or aliquot specimens. Opening the tubes destroys the vacuum seal and thus increases the risk of leakage during transport.
- Specimens for shipment should be packaged following the basic triple packaging system, which consists of (1) a primary container (a sealable specimen container) wrapped with absorbent material, (2) a secondary container (watertight, leak-proof), and (3) an outer shipping package. For questions about (packaging) transportation regulations, contact the U.S. DOT Hazardous Materials Information Center at 1-800-467-4922.

Packing and Shipping Clinical Specimens for Confirmation at CDC



The following steps should be followed by persons certified to ship infectious substances.

1. Because guidelines may vary state to state, contact your state and/or local health department prior to shipping.

2. Email tracking number to EOCEVENT246@CDC.GOV (mailto:EOCEVENT246@CDC.GOV)
3. Do not ship for weekend delivery unless instructed to do so by CDC.
4. Ship to:

Centers for Disease Control and Prevention
ATTN STAT LAB: VSPB, UNIT #70
1600 Clifton Road NE
Atlanta, GA 30333
Phone 770-488-7100

5. Include the following information inside the package: your name, the patient's name, test(s) requested, date of collection, laboratory or accession number, and CDC Form 50.34 [PDF - 1 page] (http://www.cdc.gov/laboratory/specimen-submission/pdf/form-50-34.pdf) and Viral Special Pathogens Branch specimen submission forms [PDF - 2 pages] (http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf).
6. On the **outside** of the box, specify how the specimen should be stored: **refrigerated**.
7. Include documentation required by DOT or IATA.

Occupational Health

Potential exposures to blood, body fluids, and other infectious materials must be reported immediately according to your institution's policies and procedures.

When to Contact CDC

Hospitals should contact their state and/or local health department before contacting CDC. CDC is available for consultation at 770-488-7100.

CDC will continue to evaluate new information as it becomes available and will update this guidance as needed.

Additional Resources and Information

- Instructions for Submitting Diagnostic Specimens to CDC's Viral Special Pathogens Branch (http://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html)
- Viral Special Pathogens Branch Specimen Submission Information [PDF - 2 pages] (http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf)
- Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Virus Disease in U.S. Hospitals
- HAN 364: Guidelines for Evaluation of US Patients Suspected of Having Ebola Virus Disease (http://content.govdelivery.com/accounts/USCDC/bulletins/c7bea0)

- Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008 (http://www.cdc.gov/hicpac/disinfection_sterilization/6_0disinfection.html)
- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories [PDF - 105 pages] (http://www.cdc.gov/MMWR/pdf/other/su6101.pdf)
- Submitting Specimens to CDC Specimen Submission Form (http://www.cdc.gov/laboratory/specimen-submission/form.html)

File Formats Help:

How do I view different file formats (PDF, DOC, PPT, MPEG) on this site? (http://www.cdc.gov/Other/plugins/)

(http://www.cdc.gov/Other/plugins/#pdf)

Page last reviewed: February 5, 2015

Page last updated: February 5, 2015

Content source: Centers for Disease Control and Prevention (http://www.cdc.gov/)

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) (/ncezid/dw-index.html)

Division of Healthcare Quality Promotion (DHQP) (/ncezid/dhqp/index.html)

Appendix 7

Waste Management Guidelines for Ebola Response

21 October 2014

Ebola waste is defined as any untreated medical waste generated in the care of patients with known or suspected Ebola virus disease (EVD) including, but not limited to, medical equipment, sharps, linens, used health care products, used Personal Protective Equipment, and all absorbent or un-cleanable items contaminated or potentially contaminated by a suspected EVD patient. Ebola waste is a Category A infectious substance and a Resource Conservation and Recovery Act (RCRA) hazardous waste in the State of Kansas. A RCRA hazardous waste must be transported by a registered hazardous waste transporter and disposed of at a permitted hazardous waste facility (an incinerator). Facilities need to identify such transporters and discuss their requirements prior to an incident, particularly if the facility is unable to manage Ebola waste according to WHO/UN guidelines which recommend sterilization. Ebola waste that has been treated (sterilized) by the generator using effective (autoclaving) procedures may be managed as other Category B Regulated Medical Waste (RMW) in accordance with state and federal transportation and disposal requirements.

Medical Facility WITH Autoclaving Capability	*Medical Facility WITHOUT Autoclaving Capability*
Sterilize Ebola waste in an on-site autoclave as waste is generated to avoid the accumulation of large volumes of untreated Ebola waste on-site. • Waste should be in biohazard autoclave bags and should be no more than three-fourths full. Biological and Chemical Indicators should be utilized with every autoclave cycle. • Tie bags loosely and add about 50 mL of water to each bag. • Tape a biological indicator ampoule to the outside of the bag and place bag in a metal autoclave pan or tray. (Note that effectiveness is increased with metal trays.) • Place a chemical indicator (not sterile indicator tape) near the mouth of the bag. • Autoclave contents for a minimum of 60 min, at 121°C, and 15psi, with slow exhaust. • The Autoclave log should document the contents, duration, time, pressure, and temperature for the autoclave cycle. • Document that the chemical indicator strip provides initial indication of a successful run. If the chemical indicator fails, then the sterilization should be repeated with fresh indicator. • Label the bag with the date and time of the run that corresponds with the biological indicator ampoule, autoclave log, and chemical indicator for that run. • Hold labelled autoclaved waste until the biological ampoule indicates successful sterilization. (NOTE: The biological indicator must be incubated according to manufacturer's directions for 48 hours to confirm effectiveness of the autoclave to inactivate organisms.) • AFTER biological indicator confirmation, document that bags associated with that run are ready for storage and disposal as Category B Regulated Medical Waste.	Package the waste following Department of Transportation (DOT) requirements (Title 49, Part 173.196, and other associated DOT guidance). • Properly label the packaged waste and place into secure storage. • As soon as such waste handling processes are initiated, contact KDHE's Bureau of Waste Management to obtain assistance in identifying and selecting a waste transporter and disposal facility.

Kansas Department of Health & Environment
21 October 2014

Collection and Treatment of Human Body Fluids from Isolated Patient

Human body fluids from a patient in isolation should be collected for disposal as Ebola waste or collected and treated with 1 part of household bleach to 9 parts water for at least 10 minutes or longer prior to discharge to the sanitary sewer. Facilities should discuss preferred concentrations and treatment time for bodily fluid wastes utilizing this method with their Public Waste Water Treatment facility director and local emergency manager.

Toilet bowls should be primed with 1 part of household bleach to 9 parts water based on volume in the toilet bowl prior to introduction of any wastes (i.e., prior to patient use) to ensure wastes voided during toilet equilibrium actions are appropriately treated. Body fluids expelled directly from the patient into a toilet must be treated again with 1 part of household bleach to 9 parts water for ***at least 10 minutes*** prior to discharge to the sanitary sewer; this will require consideration of the toilet bowl water volume to ensure a 1 part bleach to 9 parts of water solution is achieved during treatment.

Onsite Storage of Ebola Waste

The DOT shipping packaging satisfies the hazardous waste packaging requirement for untreated Ebola waste. Facilities unable to sterilize waste as it accumulates should have this packaging readily available.

- The outer packaging should be rigid plastic 55-gallon drums or larger over-pack plastic drums. These containers are capable of being incinerated with the contained waste.
- All DOT labeling requirements can be included on the "Hazardous Waste" label, which must also include the date the container was placed into storage (*there is a 90-day storage time limit*).
- Affix the DOT "Infectious Substance" label to the outer package.

Labeling information includes the following:

- DOT shipping name - "Infectious substances, affecting humans (Ebola Hazardous Waste)," hazardous class/division 6.2 (DOT), DOT ID # UN2814. The hazardous waste code "EBOLA" is to be put into the waste code section of the uniform hazardous waste manifest.

Additional Waste Management Resources:

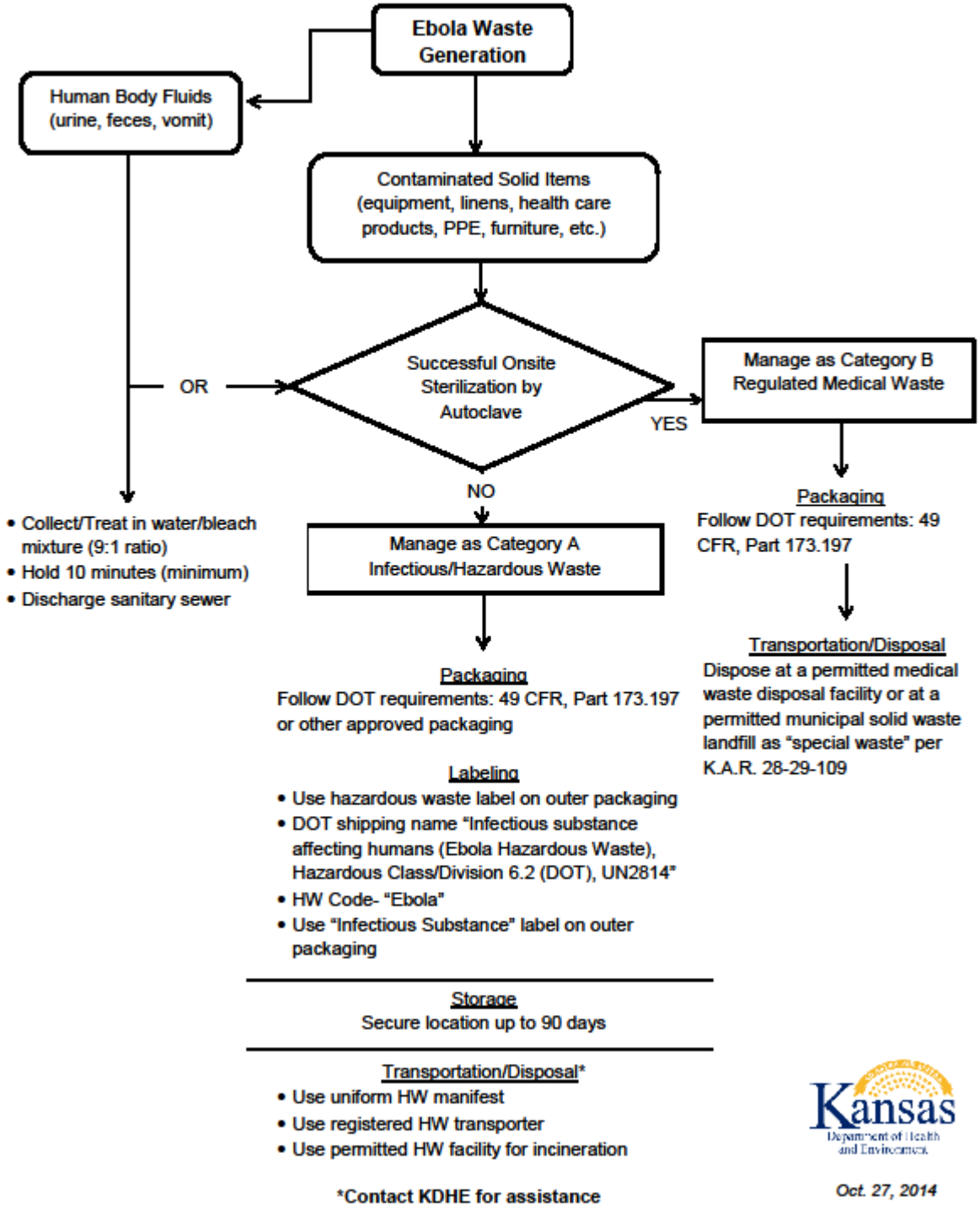
- US Department of Transportation (DOT) – Hazardous Materials Regulations (HMR, 49 C.F.R., Parts 171-180)

Additional Information on Kansas Ebola Virus Preparedness and Response Plan:

- www.kdheks.gov

Kansas Department of Health & Environment
21 October 2014

Ebola Waste Management in Kansas



Biohazardous (Ebola) Waste Storage at Generating Medical Facilities

Purpose

Any medical facility in Kansas that may generate Ebola waste or suspect Ebola waste should be prepared to properly package that waste and place it into secure storage while awaiting on-site treatment or off-site disposal. This document provides guidance regarding the packaging and storage based upon the classification of Ebola waste in Kansas (both Category A infectious waste and RCRA hazardous waste), applicable special DOT permits and regulations, KDHE's hazardous waste regulations, and likely off-site disposal options.

Note: All KDHE written and verbal guidance advises waste generating facilities to immediately contact KDHE as soon as Ebola waste or suspect Ebola waste begins to be generated to ensure that final waste management decisions are aligned with current disposal facility requirements.

Packaging Requirements

Ebola waste and suspect Ebola waste may be generated in large quantities, as much as five to ten 55-gallon containers per day per patient. The selected packaging should comply with applicable DOT shipping requirements to avoid a need for repackaging prior to shipment. The general DOT regulations for packaging Category A waste can be found at 49 CFR Part 173.196; however, a national Special Permit was issued by DOT providing alternative packaging specifically to address Ebola waste disposal at a certain facility in Texas. This Special Permit 16279 dated October 24, 2014 can be found at
http://phmsa.dot.gov/pv_obj_cache/pv_obj_id_16F699678412C96AF68A6801FF8545F63A9E0100/filename/DOT_SP_16279.pdf

KDHE recommends following the packaging guidelines found in SP-16279 because this will satisfy all on-site storage requirements as well as facilitate subsequent transportation and disposal. This would include inner packaging (a minimum of two plastic film bags) and outer packaging (a triple-walled corrugated fiberboard or poly/plastic 55-gallon container). On-site storage in properly labeled fiberboard or plastic drums would facilitate disposal as Ebola waste if testing confirms the suspicion or as other regulated medical waste if confirmation is not received. The exterior surface of the fiberboard drums should be disinfected prior to movement from the patient care area to the storage area.

Depending upon the selected off-site disposal facility, the fiberboard or plastic drums may need to be placed into large 95-gallon plastic overpack drums (also described in SP-16279).

Selection of a Storage Area

Medical facilities should select a secure area to store Ebola waste that has been packaged in the 55-gallon fiberboard or plastic drums or 95-gallon overpack drums. Secure means locked when waste is not being put into or removed from the storage area. This area should differ from any other hazardous waste storage area used by the facility.

Storage Requirements

Because Ebola waste is "hazardous" in Kansas, certain RCRA rules apply. Storage must be for 90 days or less. Every container moved into the storage area should contain labels that have at a minimum the following (1) the words "Hazardous Waste," (2) the date the container was placed into storage, and (3) an "Infectious Substance" diamond label. The final outer shipping container must also include this information plus the proper DOT shipping name: "Infectious substances, affecting humans (Ebola Hazardous Waste)," hazardous class/division 6.2 (DOT), DOT ID # UN2814 along with the Kansas hazardous waste code: "EBOLA."

Appendix 8

Sedgwick County... working for you

Emergency Medical Service

FACTS & Health

Sedgwick County Emergency Preparedness

November 2014

EMS Biosafety Transport Team

What is the Mission of the Sedgwick County EMS Biosafety Transport Team?

The mission of the Sedgwick County EMS Biosafety Transport Team (SCEMS BSTT) is to provide safe transport and quality care of patients with suspected or confirmed potentially serious infectious diseases. The SCEMS BSTT will locally provide emergency scene response for suspected patients of serious infectious diseases. Additionally the SCEMS BSTT is a Kansas deployable resource for inter-facility transports or to air evacuation points.

What are their capabilities?

The SCEMS BSTT can deploy a 7 person team to aid in the transport of a patient with a serious infectious disease to definitive care. The team is comprised of three different groups, the transport group, a decontamination group and safety officers to ensure isolation procedures are properly followed. The team is configured for the transport of a single patient and can modify their response dependent upon the suspected pathogen.

How does an agency or facility request the EMS Biosafety Transport Team?

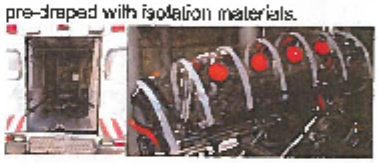
The Kansas Department of Health and Environment must authorize the transport of an infectious patient. Contact the KDHE Epidemiology Hotline **1-877-427-7317**

Once authorization has been obtained, contact the Kansas MERCs Team Dispatch at: **1-800-435-7573**

What type of equipment does the SCEMS Biosafety Transport Team use?

The BSTT is specially equipped to modify isolation precautions dependent upon the pathogens ranging from standard precautions to level III airborne precautions. Types of deployed instrumentation and equipment include:

- Dedicated ambulance with patient compartment pre-draped with isolation materials.



- Patient ISO-CHAMBER with HEPA Filtration Air Extraction System.
- 3M Breathe Easy PAPR 2.2.4 MSR Advantage 1000 Full Face Air Purifying Respirator
- Personal protective equipment including Tycham and Tyvek suits
- UV Decontamination Light
- Decontamination and waste disposal materials

Why would an agency need to request the SCEMS Biosafety Transport Team?

Prevention of disease transmission during EMS transport of patients with highly infectious diseases involves more than the proper use of personal protective equipment (PPE). It also depends on the development and implementation of appropriate administrative policies, work practices, and environmental controls accompanied by focused education, training, and supervision. The SCEMS BSTT has undertaken those tasks to ensure the safety of our clinicians and the general public by meticulous adherence to published CDC and KDHE guidance.

For more information on the team contact: dave.johnston@sedgwick.gov

Sedgwick County Community Jobs & Community Programs · 525 N. Main Suite 115 Wichita Kansas 67203 · (316) 660-1370 · www.sedgwickcounty.org

Appendix 9

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey and Certification Group

Ref: S&C: 15-10-Hospitals

DATE: November 21, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications Related to Ebola Virus Disease (Ebola)

Memorandum Summary

- ***Ebola and EMTALA requirements:*** This Memorandum conveys information useful in responding to inquiries from hospitals concerning implications of Ebola for their compliance with EMTALA.
- ***EMTALA Screening Obligation:*** Every hospital or critical access hospital (CAH) with a dedicated emergency department (ED) is required to conduct an appropriate medical screening examination (MSE) of all individuals who come to the ED, including individuals who are suspected of having been exposed to Ebola, and regardless of whether they arrive by ambulance or are walk-ins. Every ED is expected to have the capability to apply appropriate Ebola screening criteria when applicable, to immediately isolate individuals who meet the screening criteria to be a potential Ebola case, to contact their state or local public health officials to determine if Ebola testing is needed, and, when a decision to test is made, to provide treatment to the individual, using appropriate isolation precautions, until a determination is made whether the individual has Ebola.
- ***EMTALA Stabilization, Transfer & Recipient Hospital Obligations:*** In the case of individuals who have Ebola, hospitals and CAHs are expected to consider current guidance of public health officials in determining whether they have the capability to provide appropriate isolation required for stabilizing treatment and/or to accept appropriate transfers. In the event of any EMTALA complaints alleging inappropriate transfers or refusal to accept appropriate transfers, CMS will take into consideration the public health guidance in effect at the time.
- ***Centers for Disease Control and Prevention (CDC) Website*:** CMS strongly urges State Survey Agencies (SAs), hospitals and CAHs to monitor the CDC website at http://www.cdc.gov/vhf/ebola/ for the most current guidance and information concerning Ebola identification, treatment, and precautions to prevent the spread of the disease, as well as their State public health website.

Background

Due to increasing public concerns with Ebola, CMS is receiving inquiries from the hospital industry concerning implications for their compliance with EMTALA. Concerns center around

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Page 2 State Survey Agency Directors

the ability of hospitals and CAHs to fulfill their EMTALA screening obligations while minimizing the risk of exposure from Ebola infected individuals to others in the ED, including healthcare workers, and the isolation requirements for Ebola. In addition, we have also received questions about the applicability of EMTALA stabilization, transfer and recipient hospital obligations in the case of individuals who are found to have met the screening criteria for possible Ebola disease or who have been determined to have Ebola.

EMTALA requires Medicare-participating hospitals and CAHs that have a dedicated emergency department to, at a minimum:

- Provide an MSE to every individual who comes to the ED, for examination or treatment for a medical condition, to determine if they have an emergency medical condition (EMC); and
- Provide necessary stabilizing treatment for individuals with an EMC within the hospital's capability and capacity; and
- Provide for transfers of individuals with EMCs, when appropriate.

In addition, all Medicare-participating hospitals with specialized capabilities are required to accept appropriate transfers of individuals with EMCs if the hospital has the specialized capabilities an individual requires for stabilization as well as the capacity to treat these individuals. This recipient hospital obligation applies regardless of whether the hospital has a dedicated emergency department.

EMTALA Obligations when Screening Suggests Possible Ebola

It may be the case that hospitals, emergency medical services (EMS), and their State or local public health officials develop protocols for bringing individuals who meet criteria for a suspected case of Ebola only to hospitals that have been designated to handle potential or confirmed cases of Ebola. These pre-hospital arrangements do not present any conflict with EMTALA. This is the case even if the ambulance carrying the individual is owned and operated by a hospital other than the designated hospital, so long as the ambulance is operating in accordance with a community wide EMS protocol.

On the other hand, if an individual comes to an ED of a hospital or CAH, as the term "comes to the emergency department" is defined in the regulation at §489.24(b), either by ambulance or as a walk-in, the hospital must provide the individual with an appropriate MSE. We emphasize that it is a violation of EMTALA for hospitals and CAHs with EDs to use signage that presents barriers to individuals who may have been exposed to Ebola from coming to the ED, or to otherwise refuse to provide an appropriate MSE to anyone who has come to the ED for examination or treatment of a medical condition. However, use of signage designed to help direct individuals to various locations on the hospital property, as that term is defined in the regulation at §489.24(b), for their MSE would be acceptable.

If during the MSE the hospital or CAH concludes, consistent with accepted standards of practice for Ebola screening, that an individual who has come to its ED may be a possible Ebola case, the hospital or CAH is expected to isolate the patient immediately. Although levels of services

Page 3 State Survey Agency Directors

provided by EDs vary greatly across the country, it is CMS' expectation that all hospitals and CAHs are able to, within their capability, provide MSEs and initiate stabilizing treatment, while maintaining the isolation requirements for Ebola and coordinating with their State or local public health officials, who will in turn arrange coordination, as necessary, with the CDC.

At the time of the drafting of this memo, CDC's screening guidance called for hospitals and CAHs to contact their State or local public health officials when they have a case of suspected Ebola. According to that guidance, the State or local public health officials, together with the hospital, will make a determination as to whether Ebola testing of the individual is required.

- If it is determined that Ebola testing is not required, the hospital or CAH is expected to complete its MSE in accordance with accepted standards of practice and to take appropriate actions, depending on whether or not the individual has an EMC.

- If it is determined that Ebola testing is required, the hospital or CAH is expected to maintain the individual in isolation, providing treatment within its capability for the individual's symptoms as needed, until it has the test results or if, prior to test results, there is a determination by the responsible public health authorities that the case presents a strong probability of Ebola.

- If the individual tests negative for Ebola, the hospital or CAH is expected to complete its MSE in accordance with accepted standards of practice and to take appropriate actions, depending on whether or not the individual has an EMC.

- If the individual tests positive for Ebola, or the hospital together with state or local public health officials otherwise conclude that the individual likely has Ebola, even prior to obtaining test results, the hospital or CAH is expected to comply with the most recent State or local public health guidance in determining whether it has the capability to provide stabilizing treatment on site, or whether to initiate an appropriate transfer, in accordance with §489.24(e), to a hospital which has the capability to provide the required stabilizing treatment.

We appreciate the work of public health authorities, the Centers for Disease Control and Prevention (CDC) and hospitals to develop specialized capabilities to treat patients with Ebola. However, the existence of hospitals with specialized capabilities does not relieve any other hospital or CAH of its obligation to provide an appropriate medical screening examination, or fulfill any other EMTALA requirement relevant to the situation.

Other Enforcement Considerations

Should CMS receive complaints alleging either inappropriate transfers by a sending hospital or refusal of a recipient hospital to accept an appropriate transfer, it will take into consideration the State or local public health direction and designations of hospitals as Ebola treatment centers at the time of the alleged noncompliance concerning where Ebola treatment should be provided. It will also take into consideration any clinical considerations specific to the individual case(s).

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Surveyors and managers responsible for EMTALA enforcement are expected to be aware of the flexibilities hospitals are afforded under EMTALA and to assess incoming EMTALA complaints accordingly in determining whether an on-site investigation is required. They are also expected to keep these flexibilities in mind when assessing hospital compliance with EMTALA during a survey.

Consistent with their obligations under the hospital and CAH Conditions of Participation (CoPs) §482.42 and §485.635(a)(3)(vi), hospitals and CAHs are expected to adhere to accepted standards of infection control practice to prevent the spread of Ebola. Since the Ebola virus is transmitted via droplets, strict adherence to droplet and contact isolation precautions must be followed. The CDC has issued extensive guidance on applicable isolation precautions and CMS strongly urges hospitals to follow this guidance. CMS recognizes the difficulties securing the recommended personal protective equipment (PPE) required for training and patient care that may be present in some circumstances at the time of this Memorandum.

The U.S. Department of Labor Occupational Health and Safety Administration (OSHA) has also provided guidance on worker protection related to Ebola at https://www.osha.gov/SLTC/ebola/ . Hospitals and CAHs are expected under their respective CoPs at §482.11(a) and §485.608(a) to comply with OSHA requirements, but CMS and state surveyors acting on its behalf do not assess compliance with requirements of other Federal agencies.

Latest CDC Guidance

The most up-to-date guidance regarding screening, testing, treatment, isolation, and other Ebola-related topics can be found on the CDC website at http://www.cdc.gov/vhf/ebola/index.html . Hospitals and CAHs are strongly urged to monitor this site as well as their State public health website and follow recommended guidelines and acceptable standards of practice. (See also S&C 15-02: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-02.pdf) SAs are also encouraged to monitor the CDC and their state public health websites for up-to-date information.

Questions about this document should be addressed to hospitalSCG@cms.hhs.gov.

Effective Date: The information contained in this letter should be shared with all survey and certification staff, their managers, and the state/Regional Office training coordinators immediately.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management